

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters) MD-15-02641-PHX-DGC
Products Liability Litigation)
) Phoenix, Arizona
) May 30, 2018
)
Doris Jones, an individual,)
)
Plaintiff,)
) CV-16-00782-PHX-DGC
v.)
)
C.R. Bard, Inc., a New Jersey)
corporation; and Bard Peripheral)
Vascular, Inc., an Arizona)
corporation,)
)
Defendants.)

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 10 - A.M. SESSION

(Pages 2131 - 2265)

Official Court Reporter:
Patricia Lyons, RMR, CRR
Sandra Day O'Connor U.S. Courthouse, Ste. 312
401 West Washington Street, SPC 41
Phoenix, Arizona 85003-2150
(602) 322-7257

Proceedings Reported by Stenographic Court Reporter
Transcript Prepared with Computer-Aided Transcription

A P P E A R A N C E S

For Plaintiff:

Gallagher & Kennedy
By: **MARK S. O'CONNOR**, ESQ.
By: **PAUL L. STOLLER**, ESQ.
By: **SHANNON L. CLARK**, ESQ.
By: **C. LINCOLN COMBS**, ESQ.
2575 East Camelback Road, Suite 1100
Phoenix, AZ 85016

Lopez McHugh, LLP
By: **RAMON ROSSI LOPEZ**, ESQ.
100 Bayview Circle, Suite 5600
Newport Beach, CA 92660

Lopez McHugh, LLP
By: **JOSHUA MANKOFF**, ESQ.
214 Flynn Ave.
Moorestown, NJ 08057

Heaviside Reed Zaic
By: **JULIA REED ZAIC**, ESQ.
By: **LAURA E. SMITH**, ESQ.
312 Broadway, Ste. 203
Laguna Beach, CA 92651

For Defendants:

Nelson Mullins Riley & Scarborough
By: **RICHARD B. NORTH, JR.** ESQ.
By: **ELIZABETH C. HELM**, ESQ.
201 17th Street NW, Suite 1700
Atlanta, GA 30363

Nelson Mullins Riley & Scarborough.
BY: **JAMES F. ROGERS**, ESQ.
1320 Main St.
Columbia, SC 29201

Snell & Wilmer
By: **AMANDA C. SHERIDAN**, ESQ.
400 East Van Buren
Phoenix, AZ 85004

EXAMINATION**WITNESS****PAGE**

ROBERT CARR

Direct Examination (Cont'd) By Mr. North 2154

Cross-Examination By Mr. O'Connor 2160

MICHAEL RANDALL

Direct Examination By Mr. Rogers 2180

Voir Dire Examination By Mr. Stoller 2204

Direct Examination(Resumed) By Mr. Rogers 2205

Cross-Examination By Mr. Stoller 2233

Video testimony of William Little played 2261

EXHIBITS**NUMBER****DESCRIPTION****PAGE**

7900 Demonstrative depiction of
sales of Bard's retrievable
IVC filters 2156

3262 Complaint File - 03/09/2010,
263280, G2 - RF310F, 2907 2160
Detachment of device or
device component

3270 Complaint File - 03/30/2010,
266286, G2 - RF310F, 2907 2160
Detachment of device or
device component

(Index of Exhibits Continued)

EXHIBITS

<u>NUMBER</u>	<u>DESCRIPTION</u>	<u>PAGE</u>
3304	Complaint File - 07/28/2010, 282326, Eclipse - EC500J, 2907 Detachment of device or device component; 2907M Filter Limb(s)	2160
4515	Monthly Management Report, dated 4/8/10	2160
4519	Monthly Management Report, dated 8/9/10	2160
4504	Monthly Management Report, dated 4/8/09	2160
4522	Monthly Management Report, dated 11/8/10	2160
4528	Monthly Management Report, dated 5/9/11	2160
4565	FRE 1006 Chart - Plaintiff's Compilation Complaint Record Detail	2160
1680	McDonald Deposition, 07/29/2016 - Exhibit 21 - 7/13/2015 Warning Letter from the FDA	2160
802	Carr Deposition, 12/19/2014 - Exhibit 20 - NMT R&D Technical Report, RD-RPT-128, 09/01/2000, Investigation Report of a Migrated Recovery Filter in the Human Use Experience at Mt. Sinai Hospital	2165
504	Eclipse Concept POA	2168

(Index of Exhibits Continued)

EXHIBITS

<u>NUMBER</u>	<u>DESCRIPTION</u>	<u>PAGE</u>
769	Carr Deposition, 12/19/2013 - Exhibit 05 - BPV Meridian Claims Matrix, dated 7/2/2010	2173
8546	Draft Test Report re Rotary Beam Fatigue of Nitinol Wire	2210
1618	Little Deposition, 06/27/2016 - Exhibit 2005 - 4/27/2010 BPV Memo from Filter Marketing to Bill Little Re. "Filter naming", detailing the name rationale for the Eclipse and Denali	2260
2045	Sullivan Deposition, 09/16/2016 - Exhibit 431 - Marketing Brochure - G2 Filter System for Permanent Placement	2261
1617	Little Deposition, 06/27/2016 - Exhibit 2004 - Chart entitled "EVEREST/Cook Celect Clinical Comparison"	2261

P R O C E E D I N G S

(Proceedings resumed in open court outside the presence of the jury.)

THE COURT: Please be seated.

Morning, everybody.

EVERYBODY: Morning, Your Honor.

THE COURT: As you saw, I got an order out last night that ruled on the monthly management report and Rule 1006 chart issues. My conclusion was that plaintiff can present Exhibit 4519 with the filter-related complaints attached, and I think that's sufficient to show the complaints went to senior management regularly, as well as the Rule 1006 summary, which looked fine to me.

I guess one of the questions is whether defendants have any objections to the form of the 1006 summary?

MR. NORTH: No, Your Honor. We conveyed to them last night that we are okay with the summary. Well, subject to the earlier objections before the Court, of course, decided to allow the summary.

THE COURT: Yeah, you're reserving those objections. I know.

MR. NORTH: Right. As to form of this we're fine.

THE COURT: Okay. So whenever you choose to do so you can move to admit the 1006 summary and 4519.

08:32:16 1 MR. CLARK: We'll take care of those housekeeping
2 things first thing this morning, Your Honor.

3 THE COURT: Okay. I also concluded that Section 3 of
4 the FDA warning letter can come in. That, I think, is
08:32:25 5 Exhibit 1680 as redacted. So you can move that in when you
6 choose to do so.

7 I raised two questions as I was thinking about the
8 cephalad migration death issue. One to be addressed by
9 plaintiff, which is more of a concern than a question. And
08:32:42 10 the other by defendants.

11 My concern with respect to plaintiff is what was
12 characterized yesterday as a key argument in the case that if
13 the Recovery filter had been recalled, there would have been
14 no Eclipse.

08:32:57 15 I continue to be unable to see how that is part of
16 any of the claim in this case and -- well, you saw the concern
17 that I described in the order. I just want to make sure I'm
18 thinking about it clearly, so I wanted to give plaintiff an
19 opportunity to address the issue.

08:33:20 20 MR. CLARK: Your Honor, we do not intend to argue
21 that the Recovery should have been recalled. I think you've
22 correctly identified that the Recovery story is an
23 indispensable part -- those are my words, not yours --

24 THE COURT: Right.

08:33:34 25 MR. CLARK: -- of the filter history here.

08:33:35 1 What we do intend to argue, that the Recovery filter
2 was a single point of failure and that there were a number of
3 deficiencies that occurred with the development of the -- of
4 that particular filter. And we've heard a lot of testimony
08:33:50 5 about testing inadequacies from Dr. McMeeking, that this also
6 produced a design, the conical design, that is problematic for
7 a number of reasons, and we do -- and some of those issues
8 carry through, through the G2 and into the Eclipse.

9 We do try to -- and we will tie it together in our
08:34:09 10 argument, but our argument is not going to be that they should
11 have recalled the Recovery filter and therefore we would have
12 never had the Eclipse filter. But we do intend to argue that
13 had they done proper engineering and proper analysis and took
14 the information they had and used that to improve the filter,
08:34:27 15 as opposed to maintaining it on the market and kind of using
16 the sort of human test trials, that that -- I think that is
17 fair game.

18 Does that assuage your concerns?

19 THE COURT: Yes. I think that's fair argument. I
08:34:38 20 think the history of the filter development is absolutely fair
21 game when it comes to the design defect claim. So that does.
22 I had just thought yesterday it was perhaps going to be argued
23 in the way I described in the order. But that is obviously
24 incorrect.

08:34:53 25 And I put a question to defendants.

08:34:57 1 I was -- well, let me say initially that I went back
2 and I read last night the articles -- one's an article, one's
3 an FDA adverse event report, about death in morbidly obese
4 patients by other filters. I thought more about the IFU and
08:35:17 5 the reference to morbidly obese, and I don't think that opened
6 the door to further death evidence.

7 But I am concerned, as I indicated, that Dr. DeFord
8 very clearly argued, or not argued, testified to the jury that
9 the Recovery filter saved many more lives than it put at risk.
08:35:34 10 And that does seem to me, in fairness, to suggest that the
11 jury should understand that there were people who died with
12 the Recovery filter as well.

13 I'm still uncertain about this whole issue, but I
14 wanted to get defendants' response to that specific issue from
08:35:52 15 Dr. DeFord.

16 MR. NORTH: Well, first of all, we would maintain
17 that it's not the defendants that may have opened the door
18 here; it is the plaintiffs. If you go and look at the DeFord
19 transcript and which side designated which portions, large
08:36:09 20 parts of the information they're now complaining about was
21 designated by them. They asked -- they designated questions
22 asking Dr. DeFord on the criteria the company had for
23 determining whether to hold the product if migration requiring
24 surgical intervention were reported. They asked him questions
08:36:34 25 about the decision to keep on the market the product despite

08:36:38 1 the fact there were additional migrations being reported.

2 They referenced a number of questions about the company's
3 actions with regard to the number of migrations.

4 We then, in turn, designated the one point where he
08:36:52 5 says that the company still believed this was important
6 technology and was saving lives and made the decision to keep
7 it on the market. We believe that that's fair to respond when
8 they are designating all these questions.

9 They even designated a question with respect to the
08:37:10 10 Simon Nitinol, and this was testimony pled to the jury, that
11 said so when Bard was weighing do we take this off the market,
12 do we keep it on the market, and you're telling me that Bard
13 decided, well, we need to go save all these patients from all
14 these massive pulmonary embolisms that are killing people all
08:37:31 15 over the country, you had a device that was already doing
16 that; right? You had the Simon Nitinol filter.

17 They designated questions like that. And in turn we,
18 as I said, just designated a short response from Dr. DeFord
19 saying that the company weighed the risks and benefits,
08:37:49 20 acknowledging that there were reports of serious
21 complications, and that they made the decision to leave it on
22 the market.

23 I would also noted yesterday, Your Honor, they asked
24 Dr. Morris on cross-examination, they said from reading the
08:38:03 25 medical literature, you're aware that the Recovery filter had

08:38:07 1 reports of complications including complications that injured
2 patients.

3 That's on pages 1981 and -82 of the transcript, and
4 Dr. Morris acknowledged that.

08:38:19 5 So on this record, Your Honor, there's already an
6 ample amount of evidence that the Recovery filter was
7 associated with a lot of migration events. That's replete in
8 the questions they designated from Dr. DeFord. There's a lot
9 of evidence that these were serious complications. There's
08:38:37 10 even this reference that it could lead to pulmonary emboli
11 causing death and all sorts of references already.

12 We believe that they have the evidence that they
13 should be entitled to. At this point and at this stage in the
14 trial, to allow them to put in more gritty detail about death
08:38:56 15 incidents is only marginally relevant in a case which, as the
16 Court has pointed out, the legal issues at hand are the design
17 and warnings associated with the Eclipse filter.

18 So in short, they posited the entire why didn't we
19 take the Recovery filter off the market. And I would submit
08:39:16 20 that, if anything, they attempted to induce an opening of the
21 door with that.

22 And for those reasons we don't believe the door's
23 been opened and we also believe that the record has sufficient
24 evidence to rebut any argument that they believe Dr. DeFord
08:39:30 25 made.

08:39:32 1 THE COURT: All right.

2 MR. CLARK: Your Honor, I think that history is a
3 little tortured. These designations were exchanged a long
4 time ago before we had the Court's ruling on cephalad
08:39:44 5 migration death. We elected not to play this deposition. The
6 portions of the transcript that we did, we removed a whole
7 bunch of stuff from our designations. There were substantial
8 redactions made to the deposition in light of the Court's
9 ruling. But the questions we left in there, we had to in
08:40:02 10 fairness to give context to defendants' designations.

11 Again, this is a defense offered piece of evidence.
12 We did not inject this into the case. We did designate a few
13 questions to balance out and give some context to that, but we
14 were essentially hamstrung by the fact that we could not
08:40:17 15 counter the designations Bard offered to essentially tell the
16 jury, look, we're a responsible company, we continue to
17 believe that this was great technology that was saving lives,
18 and that that meant we should keep this thing on the market.
19 We couldn't put that in there that they -- in fact, they had
08:40:33 20 lots of evidence that there were a number of lives that it
21 claimed, independent of pulmonary embolism.

22 So, again, it's a sword and shield thing, Your Honor.
23 And I think fairness would require that we be allowed to put a
24 narrow amount of evidence in on this topic just to help the
08:40:48 25 jury understand that what we're talking about here when

08:40:51 1 they're looking at that is that there were, in fact, deaths.
2 And I think that is particularly important with the suggestion
3 that we believe that these things were saving lives. And we
4 heard statements yesterday about filters save lives. And,
08:41:03 5 again, we don't think there's really evidence that they do, at
6 least the retrievable filters do, in fact, save lives, but
7 that is a dispute here. But we do know that there were deaths
8 as a result of these.

9 We don't know exactly what we would do. We probably
08:41:18 10 need to see what the Court's disposition was on that. But I
11 think two to three narrow pieces of evidence that we could
12 introduce in an efficient way. We certainly don't have time
13 to do a lot more than that. But I think a couple documents,
14 perhaps a little bit of deposition testimony that we were not
08:41:33 15 able to play in light of the Court's ruling would give some
16 balance to that issue that frankly Bard has injected by
17 playing Dr. DeFord's deposition.

18 THE COURT: Do you all have a copy of the DeFord
19 deposition that shows the designations and counterdesignations
08:41:50 20 in different colors?

21 MR. CLARK: If I may approach, Your Honor.

22 THE COURT: Yeah, that would be fine.

23 MR. NORTH: I do.

24 THE COURT: That's okay.

08:42:01 25 MR. CLARK: And for the record --

08:42:01 1 THE COURT: So this is the as-played version? Is
2 this the same you have?

3 MR. NORTH: I believe so, Your Honor.

4 THE COURT: And plaintiff is red, defendant is blue.

08:42:17 5 MR. NORTH: I would draw the Court's attention
6 particularly to page 141.

7 THE COURT: Well, what I'm going to do is I'm going
8 to look at this. But what I'd also like you to think about --
9 I don't know how I'm going to come out on this. But it will
08:42:35 10 help me think about it if I have in mind what exactly you all
11 think you should be permitted to admit.

12 So if you could give some thought to that. I don't
13 need your answer right now if you need to confer about it.
14 But, say by the morning break or something. If somebody on
08:42:51 15 your team could think through that, it will help me think
16 about this in more concrete terms.

17 MR. CLARK: Your Honor, I think that would be fine.
18 The only concern we have is that my understanding is Mr. North
19 only has about ten more minutes with Mr. Carr and this is a
08:43:08 20 topic that would probably fit best with our examination of
21 him, which would happen fairly shortly.

22 I guess we could try to do some of this with
23 Mr. Modra, but I worry that he may --

24 THE COURT: Do you have only ten more minutes with
08:43:21 25 Mr. Carr?

08:43:22 1 MR. NORTH: Approximately ten to 15, Your Honor.

2 THE COURT: I'm going to impose on Mr. Carr and ask
3 him to remain until after the morning break. And that way if
4 you could give me something concrete I'll think about it and
08:43:32 5 I'll allow you to recall him for that purpose if I decide it
6 should come in. So if you could tell him I'm going to impose
7 on him in that way.

8 MR. NORTH: Sure.

9 THE COURT: So what that means is as soon as you can
08:43:46 10 come up with the idea, even if it's while we're in the middle
11 of evidence, why don't you just ask to approach, give it to
12 Nancy or give it to Traci, and I'll at least be able to see
13 and think about what it is you're proposing.

14 I also want to have a chance to look at the DeFord
08:44:05 15 deposition before I make a decision on this to decide if I
16 think the door's really been opened.

17 All right. On another issue, I read the Trerotola
18 and the Stavropoulos.

19 MR. NORTH: We call him Dr. Stav.

08:44:29 20 THE COURT: And I do not think this is excluded by
21 Rule 403 as unduly cumulative, so I'm going to overrule that
22 objection.

23 And that leaves jury instructions. Now, we're going
24 to have potentially some time at the end of the day to talk
08:44:45 25 about them. If there are other matters we need to talk

08:44:48 1 before we get started with the jury this morning, so let's
2 cover other matters if there are any before we go to jury
3 instructions.

4 MR. CLARK: None for the plaintiff, Your Honor.

08:45:00 5 MR. NORTH: None for the defendant, Your Honor.

6 THE COURT: Okay.

7 All right.

8 The purpose today is -- you saw from redlining what I
9 changed, what I didn't change. It's really just for you to
08:45:13 10 make any final comments for me to consider before we instruct
11 the jury, which looks like it will happen tomorrow morning.

12 Plaintiff's counsel?

13 MR. CLARK: Your Honor, there were a couple of
14 issues. One of them relates to instruction 14 and it's
08:45:36 15 connected to instruction 16.

16 As the Court will recall, at defendants' request, you
17 added some language to the negligent design instruction that
18 directed the jury to consider or that it should consider the
19 risk/benefit analysis for design defect about which I
08:45:54 20 previously instructed you.

21 Our concern, Your Honor, is that if the jury is to
22 consider that same analysis and were to find a negligent --
23 that Bard was negligent in the design without also finding
24 that there was strict liability for the design, then there
08:46:13 25 could potentially be an inconsistent verdict there.

08:46:16 1 I see the warning and information defect claims as
2 distinct there, for the reasons we've talked about in terms of
3 how the jury's attention was directed in the various positions
4 there, but we would -- I think in light of the Court's
08:46:29 5 inclination to include the risk/benefit language in
6 instruction 16 we think there should be language added to
7 instruction 14 essentially to the effect that, ladies and
8 gentlemen of the jury, you cannot find that the product was
9 negligently designed unless you also find that defendants were
08:46:50 10 strictly liable for a design defect. Or words to that effect.
11 And I have some proposed language.

12 My understanding is Bard does not agree to this. And
13 as long as the objection is clear on the record, we're fine
14 not including that but we just don't want there to be an issue
08:47:06 15 where this type of situation comes up and there is a potential
16 inconsistent verdict argument that we could have cured here
17 today.

18 THE COURT: I will -- I will tell you that as
19 recently as two weeks ago, three weeks ago, the Georgia Court
08:47:22 20 of Appeals -- last week the Georgia Court of Appeals issued
21 another decision saying that risk utility is part of a
22 negligent design defect analysis. So there's no avoiding that
23 legal view in Georgia which creates this ambiguity.

24 What exactly is the language you're proposing,
08:47:42 25 Mr. Clark?

08:47:44 1 MR. CLARK: Let me find it, Your Honor.

2 THE COURT: It would be where?

3 MR. CLARK: This would be at the end of
4 instruction 14.

08:47:54 5 The language I would propose adding is, quote, you
6 may not find that the Eclipse filter was negligently designed,
7 parenthesis, instruction 16, close parens, unless you also
8 find that the design of the Eclipse filter was defective.
9 Period, close quote.

08:48:29 10 THE COURT: Unless you also find --

11 MR. CLARK: That the design of the Eclipse filter was
12 defective. Period.

13 THE COURT: Wouldn't that more appropriately be in
14 instruction 16 rather than 14? Because it is an instruction
08:48:48 15 about what they can do with negligent design.

16 MR. CLARK: The way I conceptualized it, Your Honor,
17 was that it was -- we're talking about the risk utility test
18 in 14 and to -- basically that's the -- essentially, they
19 don't have to go to 16 if they don't find 14. So it made more
08:49:03 20 sense to deal with it there. I could see arguments the other
21 way.

22 THE COURT: All right.

23 And what is defendants' view on this?

24 MR. NORTH: We would like some time to think about
08:49:28 25 that if it would not impose on the Court and talk about it

08:49:32 1 right after we let the jury go, which I'm sure will be
2 midafternoon.

3 THE COURT: That's fine.

4 All right.

08:49:37 5 There was another comment, Mr. Clark?

6 MR. CLARK: One of them relates to the Court's
7 interest in looking at instruction 19 concerning damages.

8 THE COURT: Oh, that's right. We need to -- I think
9 I asked you to propose a narrowing, see if you could agree on
08:49:53 10 something.

11 MR. CLARK: You did, Your Honor, and --

12 MS. HELM: May I approach, Your Honor?

13 THE COURT: Yes.

14 MS. HELM: I apologize. Our printer has a little bit
08:50:08 15 of a streak in it, but I think you can see everything.

16 MR. CLARK: Is that the one you proposed --

17 (Counsel confer.)

18 MR. CLARK: Your Honor, we have a competing
19 instruction on that that, I guess, accepts some of it, changes
08:50:28 20 some language, and would not agree to the language on the
21 second page.

22 If I could approach?

23 THE COURT: Yes. Please.

24 So what is the red type, Ms. Helm, on yours?

08:50:45 25 MS. HELM: Your Honor, that's what we added to the

08:50:49 1 damages instruction based on the plaintiffs clarifying their
2 claims.

3 THE COURT: Okay. So that's what you've added.

4 And then, Mr. Clark, the yellow is what you want to
08:51:01 5 do with their first paragraph --

6 MR. CLARK: That's correct, Your Honor.

7 THE COURT: -- and the blue means it's not your
8 proposal?

9 MR. CLARK: We don't agree to the blue. We think the
08:51:10 10 blue really is surplusage in light of the fact that there are
11 four other instructions that talk about causation and it kind
12 of transcends into comment on the evidence.

13 THE COURT: Okay. I will look at these different
14 proposals over the lunch hour so that we can talk about them
08:51:25 15 at the end of the day.

16 What else have you got that you want to comment on,
17 Mr. Clark?

18 MR. CLARK: The last one, Your Honor, was the FDA
19 instruction. I know you've been keeping score on that. I did
08:51:37 20 want to highlight one thing, though, that I did not have in
21 front of me when we spoke the other day, and that was
22 Dr. Tillman's testimony in the morning. I think I highlighted
23 a few things from the afternoon.

24 But in the morning, she was asked the question: "And
08:51:54 25 to be clear, does the FDA make the same pronouncement with

08:51:58 1 regard to 510(k) devices like IVC filters?"

2 Her answer was: "No. It instead makes a
3 determination that the new device is as safe and effective as
4 the predicate device which is a different finding than in a
08:52:14 5 PMA."

6 The problem is, Your Honor, that that's basically
7 saying that the FDA is making a determination that the new
8 device is as safe and effective.

9 And you've looked at this a lot of different ways but
08:52:26 10 I think the way that you articulated it in your preemption
11 ruling is that the FDA does not make a determination that the
12 device is as safe and effective, it concludes the device is
13 substantially similar. And there could be safety
14 considerations that get in there but the focus is on
08:52:42 15 substantial similarity.

16 So again, with those types of things in this case, I
17 don't think it's harmful to give a corrective limiting
18 instruction, and we can certainly talk about what the language
19 is. I've gone back and tweaked what I proposed before to, I
08:52:57 20 think, address some of Mr. North's concerns about that. But
21 we do think it is very important that the jury have a very
22 clear, articulated instruction from the Court on this issue.

23 THE COURT: Do you have that language?

24 MR. CLARK: Your Honor, one second. I do.

08:53:14 25 Would you like me to read it to you? If you could

08:53:17 1 read my handwriting, I'd be happy to approach.

2 THE COURT: Have you shared it with --

3 MR. CLARK: I have not. Let me just read what it
4 is --

08:53:23 5 THE COURT: How long is it?

6 MR. CLARK: It only changes the third paragraph of
7 our proposed limiting instruction.

8 THE COURT: I don't have your proposed in front of
9 me. So why don't you share it with defendants and, if you
08:53:33 10 can, get it to me before the noon hour and I'll read that over
11 the noon hour along with the others.

12 MR. CLARK: Be happy to.

13 THE COURT: Mr. North?

14 MR. NORTH: Your Honor, if I could just briefly
08:53:45 15 respond. I believe the testimony they quoted from Dr. Tillman
16 is exactly what the FDA guidances and regulations say and what
17 this Court has cited in the past, which is that 510(k)
18 clearance involves a determination that the new device is as
19 safe and effective as the predicate device. And so I believe
08:54:02 20 that is an accurate statement of the law.

21 THE COURT: Okay.

22 Did you have -- were those all of your issues,
23 Mr. Clark?

24 MR. CLARK: They were, Your Honor.

08:54:13 25 THE COURT: Did you have instruction issues you

08:54:16 1 wanted to raise?

2 MR. NORTH: We do not, Your Honor.

3 THE COURT: Okay.

4 So what we're going to do is, plaintiffs, you'll get
08:54:25 5 to me the narrow -- I think was the word you used,

6 Mr. Clark -- proposal for Recovery filter death evidence. If
7 I decide that I'm going to permit it. And I think you'll try
8 to get it to me, if possible, sometime during the morning.

9 MR. CLARK: Your Honor, I could approach with three
08:54:46 10 documents we think we would probably offer if the Court is
11 inclined.

12 THE COURT: Yeah, just share them with defendants,
13 please.

14 MR. CLARK: It's Exhibit 1722, which is the --

08:54:56 15 THE COURT: Do you have copies?

16 MR. CLARK: I only have one copy with me. What I'll
17 do is get clean copies for defense and you.

18 THE COURT: Well, you can get them to me now because
19 I've got three minutes. Just tell him what -- tell them what
08:55:10 20 the exhibit numbers are.

21 MR. CLARK: I think Felice has extra copies --

22 Do you have extra copies right now?

23 Actually, Your Honor, I think I have them.

24 Sorry.

08:55:28 25 May I approach, Your Honor?

DIRECT EXAMINATION (CONT'D) - ROBERT CARR

08:55:49 1 THE COURT: Yes.

2 Okay. Anything else we need to address?

3 Let's take a three-minute break and then we'll get
4 the jury in here.

08:56:31 5 (Recess was taken from 8:56 to 9:00. Proceedings resumed
6 in open court with the jury present.)

7 THE COURT: Morning, ladies and gentlemen.

8 THE JURY: Morning.

9 THE COURT: Thanks for being here.

09:01:31 10 For your information, we anticipate that we are going
11 to finish the evidence today. And our plan will be to break
12 after we have finished the evidence and then to start tomorrow
13 morning with the closing arguments -- well, with jury
14 instructions and then the closing arguments of the lawyers, so
09:01:48 15 that you'll be getting the case by midday tomorrow for
16 deliberation.

17 Mr. North, you may continue.

18 MR. NORTH: Thank you, Your Honor.

19 **ROBERT CARR,**

20 recalled as a witness herein, after having been previously
21 sworn or affirmed, was examined and testified as follows:

22 D I R E C T E X A M I N A T I O N (CONTINUED)

23 BY MR. NORTH:

24 Q Mr. Carr, over your years with Bard Peripheral Vascular,
09:02:06 25 have you had involvement with the Simon Nitinol filter also?

DIRECT EXAMINATION (CONT'D) - ROBERT CARR

09:02:11 1 A Yes.

2 Q Based on your 20-plus years of experience working with IVC
3 filters, do you consider the Simon Nitinol filter a reasonable
4 alternative for a patient who would customarily receive a
09:02:21 5 retrievable filter?

6 A No.

7 Q And why is that?

8 A Because it's not retrievable.

9 Q In your experience, what are the types of patients who
09:02:30 10 typically receive a permanent filter or the Simon Nitinol
11 filter?

12 A Nowadays they'd be much older patients who may not have a
13 long life expectancy. They might be terminal in their
14 disease and really have no chance at any time of potentially
09:02:50 15 needing the filter removed.

16 Q Does Bard still sell the Simon Nitinol filter in the
17 United States?

18 A No, we don't.

19 Q And why did Bard stop selling that filter?

09:03:02 20 A The -- it didn't sell very well.

21 MR. NORTH: If we could bring up Exhibit 7900,
22 please.

23 BY MR. NORTH:

24 Q Do you recognize this exhibit, Mr. Carr?

09:03:17 25 A Yes.

DIRECT EXAMINATION (CONT'D) - ROBERT CARR

09:03:18 1 Q What is this?

2 A It's the sales from 2002 to through September of 2016 of
3 our retrievable filters and the Simon Nitinol filter.

4 Q And was this prepared at Bard as part of the business?

09:03:34 5 A Yes.

6 MR. NORTH: Your Honor, at this time we would tender
7 Exhibit 7900.

8 MR. O'CONNOR: No objection, Your Honor.

9 THE COURT: Admitted.

09:51:03 10 (Exhibit 7900 admitted.)

11 MR. NORTH: Could we display, Your Honor?

12 THE COURT: Yes.

13 BY MR. NORTH:

14 Q And does this demonstrate the low sales of the
09:03:51 15 Simon Nitinol filter as compared to Bard's retrievable filters
16 over this 15-years or 14-year period?

17 A Yes, it does.

18 Q Now, in your experience, why were Simon Nitinol filters
19 sales so low compared to the sales of the retrievable filters?

09:04:11 20 A Because the reality of it is, is the retrievable filters
21 are permanent, and if you could put a filter in that could
22 potentially be removed, because you don't always know if a
23 patient will need a filter forever, why wouldn't you do that.
24 And the Simon Nitinol filter had some nuances to it, if you
09:04:34 25 will, from a delivery point of view. And it was seen as old.

DIRECT EXAMINATION (CONT'D) - ROBERT CARR

09:04:40 1 It's probably, what, 1991 to 2016. It's a pretty old device.

2 Q And were there some sorts of complications associated with

3 the Simon Nitinol filter that gave some physicians concern?

4 A Yes.

09:04:53 5 Q And what were those?

6 A So, again, the ability to deliver it, to deploy it

7 exactly where you wanted to. Sometimes the dome, we call it,

8 the top of the filter would tilt to the side and sometimes

9 the legs would penetrate into the wall. So all known

09:05:10 10 complications.

11 Q Mr. Carr, based upon your 20-plus years of working with

12 IVC filters for Bard and previously for NMT, have you also

13 followed the marketplace in general and those companies'

14 products that compete with Bard filters?

09:05:33 15 A Generally, yes.

16 Q Are you aware of any IVC filter on the market today that

17 does not have reports of filter fracture?

18 A No.

19 Q Are you aware of any IVC filter on the market today that

09:05:42 20 does not have reports of filter migration?

21 A No.

22 Q Are you aware of any IVC filter on the market today that

23 does not have reports of filter perforation?

24 A No.

09:05:54 25 Q What about any filter on the market today that does not

DIRECT EXAMINATION (CONT'D) - ROBERT CARR

09:05:57 1 have reports of filter tilt?

2 A No.

3 Q Mr. Carr, if there were reports coming in, as we have
4 seen, of fracture incidents involving Bard's G2 or Eclipse
09:06:12 5 filters, why did the company continue to market those
6 products?

7 A Because it provided a tremendous benefit to the vast
8 majority, greater than 99.5 percent of all patients.

9 Q From your involvement in developing IVC filters, what is
09:06:35 10 your understanding in terms of the typical clinical
11 consequences of filter fracture?

12 A Usually it's -- there's not much significance, but there
13 can be.

14 Q And how do you know that?

09:06:50 15 A Over time, experience, reading articles, understanding
16 the environment.

17 Q Does Bard vigilantly review all reports that come into it
18 of filter fracture?

19 A Absolutely.

09:07:05 20 Q Now, you said that you started working with IVC filters
21 first around 1996?

22 A Yes.

23 Q During your 20-plus years, first at NMT and then at
24 Bard -- well, no, let me back up and ask you: How long was
09:07:21 25 the development process for the Recovery filter from the time

DIRECT EXAMINATION (CONT'D) - ROBERT CARR

09:07:25 1 you first began working on it at NMT until it was introduced
2 on the market by Bard?

3 A Six years.

4 Q Was there any point in time during your years at NMT and
09:07:40 5 then at Bard that the companies ever compromised the integrity
6 of the development of these devices in order to somehow rush
7 them to the market?

8 A Absolutely not.

9 Q In your experience, Mr. Carr, did Bard ever cut any
09:07:55 10 corners in the development of its retrievable filters?

11 A No.

12 MR. NORTH: Thank you. That's all the questions I
13 have.

14 THE COURT: All right. Thank you.

09:08:03 15 Cross-examination?

16 MR. O'CONNOR: Yes, Your Honor. But I think first
17 we're going to move in some exhibits into evidence.

18 THE COURT: All right.

19 MR. O'CONNOR: So I'm going to ask Mr. Clark to move
09:08:12 20 them in, and then I'll proceed to cross.

21 THE COURT: All right.

22 MR. CLARK: At this time, Your Honor, the plaintiff
23 would move into evidence Exhibits 3262, 3271 -- I'm sorry,
24 3270, 3304, 4415 as redacted, 4519 redacted, 4504 redacted,
09:08:43 25 4522 redacted, 4528 redacted, 4565, and 1680 redacted.

CROSS-EXAMINATION - ROBERT CARR

09:09:00 1 THE COURT: I'm losing a battery here, Traci.
2 Was it 4415 or 4515?
3 MR. CLARK: 4515. I apologize if I misspoke.
4 THE COURT: Okay.
09:09:12 5 THE COURTROOM DEPUTY: 4515?
6 THE COURT: 4515.
7 Ms. Helm?
8 MS. HELM: As redacted, no objections, Your Honor.
9 THE COURT: All right. Those exhibits are admitted.
09:09:22 10 (Exhibits 3262, 3270, 3304, 4515, 4519, 4504, 4522, 4528,
11 4565, 1680 admitted.)
12 THE COURT: Go ahead.
13 MR. O'CONNOR: May I proceed, Your Honor?
14 THE COURT: Yes.
11:19:09 15 C R O S S - E X A M I N A T I O N
16 BY MR. O'CONNOR:
17 Q Good morning, Mr. Carr. My name is Mark O'Connor, and I'm
18 one of the lawyers that represents Doris Jones.
19 A Good morning.
09:09:43 20 Q Let me just go back to a couple of basic points, Mr. Carr.
21 The Recovery, the G2, and the G2X were optional
22 filters; is that correct?
23 A Yes.
24 Q And that means that they were each filters that were
09:10:03 25 permanent that had the option to be retrieved. Fair?

CROSS-EXAMINATION - ROBERT CARR

09:10:06 1 A Yes.

2 Q And as for the Recovery and the G2, each of those filters
3 were first cleared on the market as permanent filters. True?

4 A Correct.

09:10:21 5 Q Thank you.

6 Now, you agree that the Recovery, the G2, and the G2X
7 should perform as well as a permanent filter. True?

8 A They are permanent filters.

9 Q Do you agree with my question that they should perform as
09:10:37 10 well as a permanent filter?

11 A I don't understand the question. They are permanent
12 filters.

13 Q Well, let me just go to your deposition, then.

14 MR. O'CONNOR: Gay, the November 5, 2013, deposition,
09:10:50 15 please.

16 BY MR. O'CONNOR:

17 Q And, Mr. Carr, do you recall this deposition? I know
18 there were others. This is your deposition, again, on
19 November 5, 2013.

09:11:02 20 Do you see that?

21 A No, I don't see any dates but I see my deposition.

22 Q All right. Will you take my word for it that it was on
23 that date?

24 A Sure.

09:11:21 25 Q Thank you.

CROSS-EXAMINATION - ROBERT CARR

09:11:23 1 And at page 41, line 11, the question was asked to
2 you: "Sir, would you agree that optional filters -- the
3 Recovery, the G2, G2 Express -- should perform as well as
4 permanent filters?"

09:11:37 5 And your answer was: "Yes."

6 Now, did I did read that correctly, sir?

7 A Yes.

8 Q Thank you.

9 During the entire time the Recovery was on the market
09:11:51 10 it was a permanent filter. True?

11 A It was an optional filter after it received that
12 indication.

13 Q Meaning it could be used as a permanent filter; correct?

14 A Yes.

09:12:03 15 Q And the same goes with the G2 and the G2X. They were --
16 the entire time they were both on the market, they were
17 permanent filters.

18 A Again, they're optional filters. There is a difference
19 between optional filters and permanent filters only.

09:12:17 20 Q But they were permanent -- in addition to optional,
21 permanent meaning that they were permanent filters that could
22 be used and indicated for permanent use. True?

23 A In addition to being optional, yes.

24 Q Now, sir, you agree that the G2 should perform as well as
09:12:37 25 the Simon Nitinol filter. True?

CROSS-EXAMINATION - ROBERT CARR

09:12:39 1 A No. I think it performs differently in certain areas.

2 Q All right.

3 MR. O'CONNOR: Gay, can we go to the deposition,
4 November 5, 2013, at page 42.

09:12:52 5 BY MR. O'CONNOR:

6 Q And, Mr. Carr, I'm looking down on page 42, line 14, you
7 were asked: "Would you agree that they should perform as well
8 as a Simon Nitinol filter?"

9 Let me put it in context.

09:13:09 10 Do you see above where the questions that were asked
11 about the G2 and the G2 Express? At line 5.

12 Let me read that.

13 "And within the context of what you just told me,
14 would you agree that the Recovery filter, the G2, and the
09:13:24 15 G2 Express should perform as well, if not better than, the
16 Simon Nitinol filter?"

17 Your answer was: "I don't know if they can perform
18 better."

19 Next question: "Would you agree that they should
09:13:38 20 perform as well as the Simon Nitinol filter?"

21 Your answer was: "Yes, they are substantially
22 equivalent."

23 Now, did I read that correctly?

24 A Yes. They are substantially equivalent. That's correct.

09:13:51 25 Q Thank you.

CROSS-EXAMINATION - ROBERT CARR

09:13:57 1 Now, the Eclipse filter was the G2X filter; correct?

2 I'm sorry. Excuse me. The Eclipse was the G2X with

3 electropolish. Is that fair?

4 A Substantially, yes.

09:14:14 5 Q What the Eclipse did was it was the G2X that added

6 electropolish. True?

7 A It's a lot more than that but, yes, it had

8 electropolishing.

9 Q And the Eclipse was a permanent filter with the option to

09:14:32 10 retrieve. True?

11 A Yes.

12 Q Sir, I want to ask you a question about the Asch study.

13 Early in that study a cephalad migration occurred with an

14 occluded Recovery filter; is that correct?

09:15:18 15 A Yes.

16 Q And you agree that you --

17 A I'm sorry, did you say cephalad? It was a cranial

18 migration.

19 Q Going up.

09:15:32 20 A Yes.

21 Q And am I correct cranial and cephalad mean the same thing?

22 A Yes.

23 Q All right. So we are -- our terminology is correct?

24 A Yes.

09:15:41 25 Q And do you agree at that time you had stated that if there

CROSS-EXAMINATION - ROBERT CARR

1 was another migration that occurred the study would be
2 stopped?

3 A I didn't state it. It was the consensus of the group
4 that was talking, I believe.

5 Q Fair enough.

6 MR. O'CONNOR: Exhibit 802, please, Gay.

7 BY MR. O'CONNOR:

8 Q Do you --

9 MR. O'CONNOR: I apologize, Your Honor. I don't
10 recall if 802 is in evidence?

11 THE COURT: It is not.

12 BY MR. O'CONNOR:

13 Q Mr. Carr, do you recall this technical report?

14 A Yes. This doesn't look like the final version, but it's
15 a draft probably.

16 Q This is a draft you're familiar with? It's a document
17 you're knowledgeable about; correct?

18 A Yes, I wrote it.

19 MR. O'CONNOR: I move to admit Exhibit 802, please.

20 MR. NORTH: No objection, Your Honor.

21 THE COURT: Admitted.

22 MR. O'CONNOR: Thank you.

23 (Exhibit 802 admitted.)

24 MR. O'CONNOR: And, Gay, if we could go to page 7,
25 please.

CROSS-EXAMINATION - ROBERT CARR

09:16:40 1 And, Gay, if you could highlight the first sentence
2 in that full paragraph, "in the end."

3 May I display to the jury, Your Honor?

4 THE COURT: You may.

09:16:55 5 BY MR. O'CONNOR:

6 Q Mr. Carr, in this report talking about that cranial or
7 cephalad migration, it was stated in the report you prepared:
8 "In the end, everyone agreed that we would continue the
9 experience at Mt. Sinai and that if another 'major' migration,
09:17:14 10 greater than 2 centimeters, occurred, we would stop the study
11 and reevaluate the filter design."

12 Now, did I read that correctly?

13 A Yes.

14 Q I want to talk a moment, Mr. Carr, again about the G2 and
09:17:37 15 the G2X, if we could.

16 Do you agree that clinical data had indicated that
17 the G2 and the G2X were tilting after placement?

18 A There were reports of tilting in the clinical trial, I
19 believe, yes.

09:17:58 20 MR. O'CONNOR: Gay, if we could go to Mr. Carr's
21 deposition dated April 17, 2013, at page 94, please.

22 BY MR. O'CONNOR:

23 Q Mr. Carr, in this deposition, at line 16, do you see where
24 I'm going to read from?

09:18:16 25 A Yes.

CROSS-EXAMINATION - ROBERT CARR

09:18:17 1 Q It's highlighted, sir.

2 Do you see that?

3 A Yes.

4 Q And the question was posed to you at that time on
09:18:22 5 April 17, 2013: "Was there clinical data indicating that the
6 G2 and the G2 Express were subsequently tilting after
7 placement?"

8 And your answer was: "Yes."

9 Now, did I read that correctly, sir?

09:18:36 10 A Yes.

11 Q Thank you.

12 Mr. Carr, do you --

13 MR. O'CONNOR: You can take that down, Gay.

14 BY MR. O'CONNOR:

09:18:42 15 Q -- you -- tilting in the G2X can lead to penetration. You
16 agree with that testimony, true?

17 A It can.

18 Q Tilting and penetration can change the stress on the
19 filter. True?

09:18:56 20 A Yes, it can.

21 Q A change in stress on the filter can lead to fracture.
22 Agreed?

23 A Yes.

24 MR. O'CONNOR: Gay, let's show Mr. Carr Exhibit 504,
09:19:10 25 please.

CROSS-EXAMINATION - ROBERT CARR

09:19:12 1 BY MR. O'CONNOR:

2 Q Are you -- you were involved in the Eclipse anchor filter
3 project; correct?

4 A Not daily, no.

09:19:30 5 Q But it's something you were aware of and had involvement
6 in. Is that true?

7 A I knew it was going on, yes.

8 Q All right.

9 MR. O'CONNOR: Your Honor, I thought 504 was in
09:19:41 10 evidence.

11 THE COURT: It is not.

12 MR. O'CONNOR: All right.

13 BY MR. O'CONNOR:

14 Q Do you recognize this document, the idea Eclipse anchor
09:19:47 15 POA?

16 A It's without a cover page, so I don't know if it's the
17 final one or a draft.

18 Q But are you familiar with the -- the document in general?

19 A I'm familiar that there is an Eclipse POA, yes.

09:20:03 20 MR. O'CONNOR: Move for its admission, Your Honor.

21 MR. NORTH: No objection, Your Honor.

22 THE COURT: Admitted.

23 (Exhibit 504 admitted.)

24 MR. O'CONNOR: And, Gay, if you could go to
09:20:11 25 Mr. Carr's deposition on April 17, 2013, at page 92.

CROSS-EXAMINATION - ROBERT CARR

09:20:18 1 BY MR. O'CONNOR:

2 Q And, Mr. Carr, the question to you was at line 13: "All
3 right, again, explain to us what your involvement was with
4 respect to the Eclipse anchor filter system."

09:20:41 5 Do you see that question?

6 A Yes.

7 Q Your answer was "I was the director responsible for the
8 development team" -- or, excuse me, "the development team
9 reported to me."

09:20:52 10 Did I read that correctly?

11 A Yes.

12 Q And this was a device that contemplated having an anchor
13 on the filter; correct?

14 A Meridian is the filter that has an anchor on it.

09:21:14 15 Q But in this project --

16 MR. O'CONNOR: Gay, let's go ahead and --

17 BY MR. O'CONNOR:

18 Q Well, let me just ask you this: The Simon Nitinol filter
19 had an anchor filter system. True?

09:21:25 20 A No.

21 MR. O'CONNOR: Gay -- well, we're right there.

22 BY MR. O'CONNOR:

23 Q The question on page 92, line 18: "Did the Simon Nitinol
24 have an anchor filter system similar to what was ultimately
09:21:41 25 used in the Eclipse?"

CROSS-EXAMINATION - ROBERT CARR

09:21:43 1 A Sorry, I thought we were referring to the anchors that
2 were added to the G2 and G2X and Eclipse filter, which are
3 downward anchors.

4 Q Let me finish, sir.

09:21:52 5 A Sorry.

6 Q In this part of the deposition you were talking about the
7 Eclipse anchor filter system. Do you recall that?

8 Do you see the question above that?

9 A Yes.

09:22:03 10 Q All right.

11 And then at line 18, the question was: "Did the
12 Simon Nitinol have an anchor filter system similar to what was
13 ultimately used in the Eclipse?"

14 Do you see where I read that from?

09:22:15 15 A I do.

16 Q Your answers was: "Similar and it had six hooks. So yes."

17 Did I read that correctly?

18 A Yes.

19 MR. O'CONNOR: And, Gay, if you would put Exhibit 504
09:22:27 20 back up.

21 May I publish to the jury, Your Honor?

22 THE COURT: Yes.

23 BY MR. O'CONNOR:

24 Q And, sir, at the time of the Eclipse anchor filter project
09:22:44 25 you were discussing at that time --

CROSS-EXAMINATION - ROBERT CARR

09:22:46 1 MR. O'CONNOR: Under Summary, Gay, "the application
2 of caudal anchors." Highlight that, please.

3 At the top under Summary. Second sentence there.

4 Thank you.

09:23:04 5 And -- well, let's just read the second sentence, the
6 first sentence, Gay.

7 Go ahead and highlight the entire summary.

8 BY MR. O'CONNOR:

9 Q It says: "This POA" -- which is a product opportunity
09:23:29 10 appraisal, is that correct, Mr. Carr?

11 A Yes.

12 Q "This POA describes the addition of anchors to the Eclipse
13 filter. Feedback from customers, the field, and our own
14 clinical data have shown an increased frequency of migration
09:23:42 15 in the caudal direction with the G2 and G2X filters as
16 compared to the Recovery."

17 Did I read that correctly?

18 A Yes, you did.

19 Q "The application of caudal anchors would potentially
09:23:55 20 eliminate this failure mode and reduce tilting of the filter."

21 Did I read that correctly?

22 A Yes, you did.

23 Q And you were talking about a project where there would be
24 an addition of caudal anchors. True?

09:24:09 25 A Yes.

CROSS-EXAMINATION - ROBERT CARR

09:24:09 1 Q All right.

2 MR. O'CONNOR: Gay, go down to Problems section.

3 BY MR. O'CONNOR:

4 Q And according to this document, the project that you were
09:24:20 5 the director on, it was stated that "Filter movement may lead
6 to tilting, undesirable cava wall incorporation, increased
7 risk of filter fracture, and vena cava penetration."

8 Did I read that correctly?

9 A Yes, you did.

09:24:36 10 Q And this was a project that was evolving while the Eclipse
11 filter was on the market. True?

12 A Yes.

13 Q Thank you.

14 And the Eclipse filter was released in January of
09:24:51 15 2010; correct?

16 A I don't know.

17 Q Does that sound about right, sir?

18 A I don't know.

19 Q If that's been the testimony, you don't have any reason to
09:25:01 20 disagree with that. True?

21 A Sure.

22 Q Thank you.

23 The Meridian filter was also being involved around
24 that time; correct?

09:25:14 25 A That is the POA for the Meridian filter.

CROSS-EXAMINATION - ROBERT CARR

Q All right. Then let's show -- let me show you 769.

This is a document dated July 2, 2010, entitled
"Meridian Claims."

Do you see that?

A Yes, I do.

Q All right. And so what you're telling us is that the
Eclipse anchor project was the same as the Meridian?

A It's the name. Yes.

Q All right. And you've seen this document before, haven't
you?

A I don't know that I have but I guess I did at a previous
testimony.

MR. O'CONNOR: Move to admit 769 into evidence,
please.

MR. NORTH: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit 769 admitted.)

BY MR. O'CONNOR:

Q The Meridian IVC filter was designed to resist caudal
migration and thereby decreasing the likelihood of penetration
to occur; is that correct?

A Yes.

Q And those design features were discussed back in time of
when the G2, G2X, and Eclipse were on the market. Fair?

A Yes.

CROSS-EXAMINATION - ROBERT CARR

09:26:25 1 MR. O'CONNOR: May I publish this, please,
2 Your Honor?

3 THE COURT: Yes.

4 BY MR. O'CONNOR:

09:26:34 5 Q And then if we go to paragraph F on this document, it
6 says: "The Meridian IVC filter is designed to resist caudal
7 migration, decreasing the likelihood that fracture to occur."

8 Did I read that correctly?

9 A Yes. There's an asterisk, it appears, though. I don't
09:26:55 10 know what that goes to.

11 Q Well, there's "small print" there. Do you see where it
12 says that?

13 A Yes.

14 Q All right.

09:27:01 15 MR. O'CONNOR: Gay, highlight that.

16 BY MR. O'CONNOR:

17 Q And what that goes on to say is that: "Based on clinical
18 evidence from the EVEREST trial, when migration and tilt are
19 present, there is a higher probability for fracture to occur."

09:27:15 20 Did I read that correctly?

21 A Yes, you did.

22 Q Thank you.

23 Now, Mr. Carr, I heard you on direct examination talk
24 about the amount of money over the years that Bard invested in
09:27:38 25 research and development for IVC filters. Do you recall that

CROSS-EXAMINATION - ROBERT CARR

09:27:44 1 testimony?

2 A Yes.

3 Q And I think you also talked about the amounts of money
4 that were invested for marketing; correct?

09:27:53 5 A Yes.

6 Q Bard was very invested in the success of IVC filters.
7 True?

8 A Yes.

9 MR. O'CONNOR: Gay, show Mr. Carr Exhibit 4519.

09:28:21 10 And let's go to page 5 of that document.

11 Your Honor, I believe 4519 is in evidence.

12 THE COURT: Correct.

13 MR. O'CONNOR: May I display to the jury, please?

14 THE COURT: Yes.

09:28:37 15 BY MR. O'CONNOR:

16 Q Mr. Carr, what we're looking at is a memorandum, also
17 known as a Monthly Management Report, dated August 9, 2010.

18 Would you like to see the first page?

19 A Yes, please.

09:28:51 20 MR. O'CONNOR: Gay, would you please go back to the
21 first page for Mr. Carr.

22 Thank you.

23 And now go to page 5.

24 BY MR. O'CONNOR:

09:29:02 25 Q And the Monthly Management Report, as you saw, was written

CROSS-EXAMINATION - ROBERT CARR

09:29:09 1 by Tim Ring. And who is he, sir?

2 Who is Tim Ring?

3 A I don't think it was written by Tim Ring.

4 Q I'm sorry. It was directed to Mr. Ring.

09:29:19 5 Who is Mr. Ring?

6 A He was the CEO -- president, CEO of the company.

7 Q And it was from Jim Beasley. Who is Mr. Beasley?

8 A He was the president of our division.

9 Q Important people at Bard; correct?

09:29:34 10 A We're all important.

11 Q I believe that.

12 And going to page 5, you see at the top there, there
13 is a row that talks about or titled "Key Product Line Sales
14 Per Day."

09:29:54 15 Do you see that?

16 A Yes, I do.

17 Q And then it reports for the months in 2010.

18 Do you see where I'm referring to?

19 A Yes.

09:30:03 20 Q And it indicates sales per day.

21 Are you following me?

22 A Yes.

23 Q And according to this exhibit, in February of 2010, there
24 were, for example, 2,000- -- excuse me, 219 filters sold per
09:30:22 25 day during that month of February.

CROSS-EXAMINATION - ROBERT CARR

09:30:24 1 Do you see where I'm reading?

2 A I don't think that's correct, no.

3 Q Well, do you have any reason to dispute this document?

4 A No. But the title is "Sales" and there's thousands of
09:30:37 5 dollars listed on the left. So I think that's dollars, not
6 units. Without seeing the rest of it.

7 Q So you think that what is said is that 219 means 219
8 thousands of dollars?

9 A I haven't seen the document before, so what's not
09:30:55 10 redacted, I would assume that's dollars.

11 Q All right. With three zeros after it?

12 A Yes. But, again, I don't know.

13 Q All right. Well, if we interpret the way you have -- and
14 thank you for that clarification.

09:31:07 15 So if we assume it's your interpretation, during the
16 month of February of 2010 there would have been \$219,000 of
17 filter sales; correct? If we interpret the way you just did.

18 A Again, without seeing the rest of the document, yes.

19 Q And if we go through all the way until July, in July, for
09:31:30 20 example, 2010, there was \$213,000 of filter sales for that
21 month alone. True?

22 A Yes.

23 Q All right. Thank you.

24 (Counsel conferring.)

25

CROSS-EXAMINATION - ROBERT CARR

09:31:42 1 BY MR. O'CONNOR:

2 Q Oh. Excuse me. Let me just clarify something. I was
3 just reminded of something.

4 The numbers that we're looking at are per day, if you
09:31:58 5 read the top title, not per month.

6 Do you see that?

7 A I do, yes.

8 Q All right. So per day. We would be looking at, in the
9 month of February, 219,000 per day.

09:32:08 10 Do you see where I'm reading?

11 A I do, yes.

12 Q And that's a fair interpretation of this document;
13 correct?

14 A Without seeing the rest of it, yes.

09:32:17 15 Q And then if we go all the way through just by way of
16 example, July of 2010, filter sales generated in that month,
17 \$213,000 per day in the month of July. True?

18 A That's what it says.

19 Q All right. And so we could -- assuming this document is
09:32:38 20 correct, we could calculate those amounts and figure out how
21 much each month in, for example, 2010 Bard was making from
22 filter sales, true?

23 A Yes.

24 Q So, for example, in July, the number of days times 213,000
09:32:55 25 would give us an indication of the total amount in July of

CROSS-EXAMINATION - ROBERT CARR

2010 that Bard made for filter sales; correct?

A Of course.

Q Sir, one other area. When you were talking about FEA and stress and strain tests with Mr. North, do you recall that testimony?

A Yes.

Q There was an FEA analysis that dealt with the strains that were on the filter when it was in the delivery tube; is that right?

A Partially, yes.

Q And that's different than stresses and strains when the filter is actually in the vena cava. True?

A Yes. That's why we did both.

Q But just so we're clear, stresses and strains, the FEA you discussed, you discussed an FEA that dealt with stresses and strains while the filter was in the delivery tube. You do recall that. True?

A It's both, sir. It's both cases.

MR. O'CONNOR: That's all I have, Your Honor. Thank you.

THE COURT: Redirect?

MR. NORTH: Nothing further, Your Honor.

THE COURT: All right. Thank you, sir. You can step down.

MR. ROGERS: Your Honor, at this time the defense

DIRECT EXAMINATION - MICHAEL RANDALL

calls Michael Randall.

THE COURT: If you want to stand up, ladies and gentlemen, while he's coming in, feel free.

THE COURTROOM DEPUTY: Go ahead and take a seat.

MICHAEL RANDALL,

recalled as a witness herein, after having been previously sworn or affirmed, was examined and testified as follows:

D I R E C T E X A M I N A T I O N

BY MR. ROGERS:

Q Good morning, Mr. Randall.

A Good morning.

Q The jury had a chance to meet you briefly last week. Would you mind reintroducing yourself, please.

A Sure. My name is Michael Randall. I'm a director for research and development and I oversee the vena cava filter franchise right now.

Q Are you an engineer by training?

A Yes. Mechanical engineer.

Q Can you give us a brief rundown of your educational background?

A Sure. I'm a mechanical engineer, graduated from University of California, Irvine. And then also I have an MBA in international business from Thunderbird School of Global Management.

Q How long have you lived in the Phoenix area?

DIRECT EXAMINATION - MICHAEL RANDALL

09:35:59 1 A About 12 years.

2 Q Do you have a family?

3 A Yes, I do.

4 Q Can you tell the jury about your family?

09:36:04 5 A Yes. So me and my wife, we've been together for over 27
6 or some-odd years, and we have three boys. And we relocated
7 out from California here and actually enjoy the Phoenix area.

8 Q Did you move to Phoenix in order to come work for Bard
9 Peripheral Vascular?

09:36:25 10 A Yes, I did.

11 Q And was Bard the first medical device company that you
12 worked for?

13 A No. I started my medical device career at Baxter
14 Healthcare in California. And then also Edwards Life
09:36:38 15 Sciences. So about 23 years in the med device industry.

16 Q And have you been involved in the medical device industry
17 for your entire professional career?

18 A Yes.

19 Q Can you please tell the jury how you got into that? What
09:36:52 20 was your reason for getting into the industry of medical
21 devices?

22 A Yeah. So initially, I wanted to be a physician. I
23 wanted to be a interventional cardiologist. And, you know,
24 the year before I graduated I had my first son and, you know,
09:37:09 25 I got my degree and I kind of felt that it was -- I should

DIRECT EXAMINATION - MICHAEL RANDALL

09:37:12 1 probably start working as an engineer. And engineers get
2 paid, you know, decent, so I kind of stuck with it, but I
3 wanted to stay with medical devices. That way, you know,
4 instead of treating patients, I can design products to help
09:37:27 5 patients.

6 Q And during the time that you've been at Bard, what are
7 some of the types of products that you've worked on?

8 A I've worked on, of course, vena cava filters, I've worked
9 on PTA balloons which expand arteries and veins. Also
09:37:46 10 stents. Crossing devices, a device used to cross a occluded
11 artery. Those are -- those are -- oh. Some embolization
12 things for cancer, too, as well.

13 Q And, Mr. Randall, what year did you come to Bard?

14 A 2006.

09:38:07 15 Q And when you came to Bard in '06, did you start working on
16 IVC filters as soon as you got there?

17 A No. Not right away. I was working in the PTA franchise,
18 the balloon franchise.

19 Q And so when did you start working with IVC filters?

09:38:23 20 A I was -- about 2007, beginning 2007.

21 Q Mr. Randall, did you have any role in the -- with the
22 Recovery filter?

23 A No.

24 Q And did you have any involvement with the G2 filter?

09:38:38 25 A No, I did not.

DIRECT EXAMINATION - MICHAEL RANDALL

09:38:40 1 Q And so what was the first Bard IVC filter that you played
2 a role in on a day-to-day basis?

3 A It was the G2X filter. And that was a filter where we
4 were adding a snarable retrievable tip to the apex of the
09:38:57 5 filter and making some delivery system modifications.

6 Q And have you worked on the subsequent generations of the
7 Bard IVC filters?

8 A Yes, I have.

9 Q Mr. Randall, I want to kind of change up a little bit and
09:39:10 10 talk to you about the inferior vena cava itself.

11 A Um-hmm.

12 Q And as part of your work on Bard filters, have you done
13 any personal research in order to learn about the inferior
14 vena cava?

09:39:26 15 A Yes. We've done a lot of research.

16 Q And describe for us what you've done. What are the types
17 of things?

18 A Well, you first start off with trying to find everything
19 that's out there that's known that's been published. So
09:39:40 20 journal publications, case studies by physicians, different
21 universities have done different types of experiments. So
22 you start off with that.

23 Then after that you want to talk to the experts in
24 the field. So KOLs, or key opinion leaders. So different
09:40:01 25 physicians who are known worldwide to be experts in this

DIRECT EXAMINATION - MICHAEL RANDALL

09:40:04 1 field. So you talk to those people.

2 You also do experiments on your own. Animal studies.
3 Things like that.

4 Q And did you yourself volunteer for some testing in order
09:40:17 5 to learn about the inferior vena cava?

6 A Yeah. Actually, it was myself and four of my engineers.
7 We went to HR and we said, hey, we want to rent an MRI,
8 because it's safe, it's not like radiation, and they said,
9 yes, you can do it. You have to sign a waiver.

09:40:37 10 So four of my engineers, myself, went down and jumped
11 in an MRI and we started measuring our IVCs in different
12 locations. We did it in a supine and in a prone position. So
13 laying on your back, and then laying on your stomach.

14 And then we also did things where we beared down to
09:40:57 15 do a Valsalva maneuver, kind of like when you're pushing in,
16 like doing a bowel movement or if you cough.

17 So we did different things like that to try and learn
18 about the vena cava.

19 Q And what sorts of things did you learn about the inferior
09:41:13 20 vena cava based on the research?

21 A Yeah. So the vena cava, it is unlike your aorta, which
22 is the main artery that blood comes -- leaves your heart and
23 goes out of. The vena cava is a -- kind of like an oval
24 shape vessel. It's -- it -- it's constantly changing shape
09:41:35 25 when you breathe. And then when you bear down to do a

DIRECT EXAMINATION - MICHAEL RANDALL

09:41:38 1 Valsalva maneuver, you're actually able to flatten out your
2 vena cava.

3 So those are some of the things that we learned from
4 that.

09:41:48 5 Q And, Mr. Randall, if the jury has heard some implications
6 in this trial that Bard did not understand the dynamics of the
7 inferior vena cava, how would you respond to that?

8 A I would say Bard is, in my opinion, the leading expert in
9 vena cava. They were the first to come out with a
09:42:09 10 retrievable vena cava filter. They understand the dynamics
11 to the best they could, given the technology that's available
12 at that time.

13 So I say even to this day I still believe we are the
14 leaders in this space.

09:42:27 15 Q Is it fair to say that over the course of your 12 years or
16 so at Bard that your knowledge and Bard's knowledge of the IVC
17 has continued to grow?

18 A Yes. Absolutely.

19 Q I think you mentioned this a moment ago, but are you able
09:42:39 20 to do things today that you couldn't have done 12 years ago to
21 learn about the IVC?

22 A Yes. There's different technologies, different imaging
23 that's available. And there's different things you can do to
24 learn about the IVC. So as time moves forward, you learn
09:42:58 25 more. And you take what you learn and you make improvements.

DIRECT EXAMINATION - MICHAEL RANDALL

09:43:03 1 Q And have you taken the information that you have learned
2 and tried to sort of bring that to the development of
3 different generations of IVC filters?

4 A Yes. As we learn new technologies -- also in
09:43:16 5 manufacturing processes. There's different ways to
6 manufacture something, and then there's always new technology
7 on how to improve manufacturing.

8 So as we heard -- as we got new technologies to
9 manufacture, as we got new information about caval dynamics,
09:43:32 10 you're constantly trying to innovate and incorporate those
11 into your next generation filters.

12 Q What sorts of challenges as far as the design of an
13 inferior vena cava filter is concerned do you run into as an
14 engineer who is trying to develop and improve the IVC filters?

09:43:49 15 A You know, there's a lot of things that you have to
16 consider. It's a balance of different attributes. For
17 instance, in order for the filter to really stay in place, it
18 has to have radial strength. So basically how strong the
19 filter pushes and exerts force against the vena cava. That
09:44:09 20 keeps it from kind of from moving up and down.

21 Well, if it's too strong, what happens is, is the
22 filter can start going -- growing out of the cava wall. I
23 guess the best analogy for that is kind of like you have a
24 fence and a tree next to it, and the tree wants to grow and
09:44:29 25 sometimes the tree will grow through the fence. That's the

DIRECT EXAMINATION - MICHAEL RANDALL

09:44:32 1 same with the vena cava. So if you have too much radial
2 strength it could cause what we refer to as transmural
3 incorporation, basically grow out of the vena cava wall.
4 That's for radial strength.

09:44:44 5 There are other things that you have to consider,
6 such as how you make your anchors. So you want your anchors
7 to be able to hold the cava in place -- excuse me, hold the
8 vena cava filter in place, but you also want to make it
9 retrievable so when you retrieve it, it pulls out.

09:45:02 10 So if you make an anchor that has a closed cell
11 design, closed cell design means all sides are attached, and
12 then you get tissue incorporation over it, then when I go to
13 pull it, I have to shear off that material. So you're kind of
14 limited to an anchor that is not a closed cell design. That
09:45:21 15 way, when you pull it out, it's like taking a sock off almost.
16 You don't rip the tissue. So that's like, you know, radial
17 strength, anchors.

18 And then --

19 Q Let me stop you for just a second. When you're talking
09:45:35 20 about these anchors, are you talking about what might be
21 described as the hooks at the bottom --

22 A Yes.

23 Q -- of the filter?

24 A Yes.

09:45:42 25 Q Okay. Because the jury's heard some about caudal anchors

DIRECT EXAMINATION - MICHAEL RANDALL

09:45:44 1 and then also anchors like the hooks. And can you distinguish
2 between those two things?

3 A Well, we refer to caudal anchors as an anchor that points
4 downward. And it's an anchor that's designed to keep the
09:45:58 5 filter from moving in the down direction.

6 And the cranial anchor points upward, so when it
7 grabs tissue it prevents it from moving upwards. But it's
8 flexible enough that when you retrieve it, it will release.
9 So there's kind of a fine balance there.

09:46:15 10 Q When you are designing a retrievable filter, what are some
11 of the issues you run into as far as the thickness of the arms
12 and legs and the structure of the filter?

13 A Yeah. If the filter is too thick, that affects the
14 radial strength; it can be too strong, it can be bulky and
09:46:34 15 have a lot of material. It can be hard to retrieve. If
16 there's too much thickness material in there it could also
17 cause a negative effect and can be thrombogenic, meaning it
18 could want to cause a clot. So you've got to be careful with
19 that.

09:46:53 20 Q And how about the span or the width of the legs or arms of
21 filter, what issues did those bring to the table?

22 A Yeah. So the span is essentially, you know, the width of
23 the filter, of the arms. You make it too small, you can run
24 into issues where you can get some tilting or you can get
09:47:11 25 some movement up.

DIRECT EXAMINATION - MICHAEL RANDALL

09:47:12 1 If it's too big, then I'm making this angle in the
2 neck too flat, and then if I have deflection it could cause
3 increased stresses.

4 So there's things to consider when you look at the
09:47:25 5 dynamics of the cava, you look at residual stresses or cyclic
6 stresses in the neck.

7 So like I'd said, it's a fine balance.

8 Q And what are the types of things that Bard has done in
9 order to address some of these challenges?

09:47:43 10 A On the filters?

11 Q Yeah. By that, I mean as far as developing methods of
12 testing and developing new products.

13 A So, I mean, we came up with this -- the test that really
14 strikes me the most is probably one of the tests I'm really
09:47:59 15 proud of. It's -- we came up with this test, and it's a tube
16 that we have simulated cava tissue in. And we pressurize it,
17 causing the cava to flatten out. But then also with this
18 tube, we have pistons hooked up to it and we can cause the
19 tube to stretch and collapse.

09:48:19 20 So what we do is we put filters in it and we try to
21 make them tilt, move up, move down, and then we use that test
22 to design filters that resist, you know, tilting, moving up
23 and down.

24 So that is kind of one of the -- one of the really
09:48:38 25 novel tests that no manufacturer has that we put together to

DIRECT EXAMINATION - MICHAEL RANDALL

09:48:42 1 help us design next generation filters.

2 Q Mr. Randall, let's talk a little bit about the projects
3 that have gone on at Bard as far as filters are concerned.
4 And this case involves an Eclipse filter.

09:48:57 5 And can you tell the jury when the project to design
6 the Eclipse filter kind of kicked off?

7 A I believe Eclipse kicked off in 2008, 2009 time frame,
8 around there.

9 Q And before the Eclipse, was the product that was on the
09:49:13 10 market the G2X?

11 A Yes, it was.

12 Q And before that, was it the G2 filter?

13 A Yes, it was.

14 Q And so when you got to Bard, did you do some looking back
09:49:26 15 to kind of review documents and figure out what had been done
16 before you arrived as far as the development of filters?

17 A Yeah. I looked at the G2 folder because that was the
18 predicate device, and then we're making enhancements to that.
19 So I looked at the design history file there.

09:49:47 20 Q And, very briefly, can you tell us what some of the other
21 projects are that you worked on as far as either filters that
22 were developed for the market or potential filters that didn't
23 make it?

24 A Oh, yeah. There were quite a bit.

09:50:01 25 So there's G2X, that was the first one I was on.

DIRECT EXAMINATION - MICHAEL RANDALL

09:50:05 1 There was also G3, which was the next generation platform.

2 There was a project called G2 Platinum, then Eclipse, and then
3 simultaneously there was the Meridian filter, and then also
4 the Denali filter.

09:50:24 5 MR. ROGERS: And can we pull up Exhibit 8482, please.

6 BY MR. ROGERS:

7 Q Mr. Randall, on your screen right now you have got a
8 timeline that shows the various dates of the development of
9 the projects that you were just describing.

09:50:45 10 Was this timeline made at your direction?

11 A Yes, it was.

12 Q And did you have input in the creation of this timeline?

13 A Yes, I did.

14 Q And would this timeline assist you in describing for the
09:50:57 15 jury when these various projects were taking place?

16 A Yes.

17 MR. ROGERS: Your Honor, at this time I move that we
18 be allowed to display this timeline for demonstrative
19 purposes.

09:51:08 20 MR. STOLLER: No objection.

21 THE COURT: You may.

22 BY MR. ROGERS:

23 Q All right. Mr. Randall, let's kind of go through these a
24 little bit one by one. And over there on the far left we can
09:51:17 25 see that there is the Recovery filter.

DIRECT EXAMINATION - MICHAEL RANDALL

09:51:19 1 Do you see that?

2 A Yes, I do.

3 Q And you obviously did not work on the Recovery filter.

4 A No, I did not.

09:51:25 5 Q But does this accurately represent about when the Recovery
6 filter was in development?

7 A Yes. Development to commercialization.

8 Q And then the next one we have is the G2 filter. Again,
9 you didn't work on that; right?

09:51:38 10 A No, I did not.

11 Q But do you think that this timeline accurately reflects
12 the time period where the G2 filter was under development?

13 A Yes, I do.

14 Q And so the next thing we see is a time point in April of
09:51:50 15 2006 for the G3 filter.

16 Do you see that?

17 A Yes.

18 Q And can you describe that project for the jury?

19 A The G3 filter was essentially the next generation vena
09:52:04 20 cava filter. The team was allowed to make changes to
21 thicknesses, shapes, anchors, and they really were trying to
22 benchmark against all of the other filters there.

23 And this particular filter project, it was
24 anticipated there would be a clinical study for this because
09:52:30 25 it was kind of like a really big revamp or a complete platform

DIRECT EXAMINATION - MICHAEL RANDALL

09:52:34 1 design.

2 Q And so what happened with that project?

3 A There were some animal studies conducted. And based on
4 the results of the animal studies, we saw increased
09:52:46 5 penetration in animals. So that project was put on hold
6 indefinitely.

7 Q Well, the next thing we have is the G2X. And I believe
8 you told us that you did work on that project?

9 A Yes, I did.

09:52:58 10 Q And does this accurately represent the time period where
11 the G2X was being developed?

12 A Yes, it does.

13 Q All right. And so let's move on to the Platinum project.

14 And can you tell us about that?

09:53:12 15 A So the Platinum project, we were going to take the G2X
16 filter, and we started looking at things initially with
17 improving fatigue resistance, and then at the very beginning
18 of the project we were thinking about, okay, what can we do
19 for improving migration resistance caudally, and improve
09:53:37 20 tilt. So when we initiated this project we were going to
21 terminally electropolish the filter. So terminally means
22 it's the last step. And then we put it in an electropolish
23 bath and that would help improve fatigue resistance. That
24 was the main goal. But we never got past that step and that
09:53:59 25 project was put on hold.

DIRECT EXAMINATION - MICHAEL RANDALL

Q And just so we're clear, when you say "terminally," do you mean that the entire filter at the end of manufacturing process would be electropolished?

A Yes.

Q And what was your role with this project, the Platinum project?

A Initially, I kicked it off as the project leader, and then kind of provided support for the oncoming project leader.

Q And, Mr. Randall, the jury's heard a little bit about electropolishing, but could you remind us what that is.

A Sure. Electropolishing is like an electrical chemical process, and what it does is it removes fine micro imperfections off of the surface of Nitinol. If you were to look at it with an unaided eye, you couldn't tell the difference.

And then when you do this process, it will actually make the Nitinol shiny like silver or platinum. That's why it was called Platinum, because we were going to terminally electropolish. But it basically removes micro imperfections to help improve fatigue resistance.

MR. ROGERS: Scott, can we take this down and pull up Exhibit 4430.

And, Your Honor, may we publish? This is in evidence.

DIRECT EXAMINATION - MICHAEL RANDALL

09:55:18 1 THE COURT: Hold on just a second.

2 THE COURTROOM DEPUTY: 4430 is admitted.

3 THE COURT: Yes, you may.

4 MR. ROGERS: Oh, I'm sorry. Thank you.

09:55:25 5 And can you go to the second page, please.

6 Next page.

7 Here we go.

8 And can you pull that out, those two pictures.

9 Thank you.

09:55:38 10 BY MR. ROGERS:

11 Q And so, Mr. Randall, if you would, kind of take us through

12 what we're seeing here and describe for us about the

13 differences between the two photos.

14 A Yeah. So the image to the left, the nonelectropolished

09:55:51 15 wire, you can see on that surface there, there's kind of like

16 some blemishes of the Nitinol. And this is really normal

17 from extrusion. And these are polished mechanically. If you

18 were to look at this with an unaided eye, you wouldn't see

19 these. But this is, you know, 20 micron, micrometers. If

09:56:14 20 you look at the scale on the bottom, that little black line,

21 the 20 micrometers there, that's like point -- I'll put it in

22 terms of inches. It's like .0008. So, I mean, it's small.

23 So that kind of gives you the relative scale how zoomed up we

24 are.

09:56:30 25 The image on the left is that same wire after you

DIRECT EXAMINATION - MICHAEL RANDALL

09:56:34 1 undergo an electropolishing process. And what it does is it
2 really smooths out those imperfections. And the reason that's
3 important is because, you know, when you have any type of
4 cyclic loading, typically cracks or fatigue start at
09:56:56 5 imperfections. So the smoother you can make it, the more
6 fatigue resistant the material will be.

7 Q And before we move on from this, were these photographs
8 taken with a microscope?

9 A It was taken with a scanning electron microscope. So
09:57:11 10 that is probably one of the most powerful microscopes.

11 Q And before you started working on the project to
12 electropolish an IVC filter, had you had previous experience
13 with other medical devices and electropolishing?

14 A Yeah. So I have a really strong background in Nitinol
09:57:31 15 implantable devices. Previously at my other employer I
16 worked on stents, Nitinol self-expanding stents, and those
17 stents had electropolishing on it. So I was very familiar
18 with electropolishing.

19 Q And you mentioned this a moment ago, but was the goal of
09:57:53 20 electropolishing to improve fatigue resistance?

21 A Yes, it was.

22 Q And did you believe that electropolishing would completely
23 eliminate any potential fracture with IVC filters?

24 A No. We did not believe that. I think -- and I've got a
09:58:11 25 lot of experience in this industry. Anything that you

DIRECT EXAMINATION - MICHAEL RANDALL

09:58:16 1 implant that sees a dynamic load, whether it's stents, it's
2 vena cava filters, balloon expandable stents, they will
3 exhibit fracture. There's no such thing as a fracture-proof
4 product like that. Now, very small amount of fracture, but
09:58:35 5 still. To eliminate it completely, no, we do not believe
6 that.

7 Q And what sorts of issues did you run into when -- with the
8 project Platinum that -- where you were trying to
9 electropolish the entire filter at the end of the
09:58:50 10 manufacturing process?

11 A Yeah, so the Platinum project, like I said, this
12 electropolishing process removes a small amount of material.
13 So what was happening since we were doing it at the end of
14 the process, the electropolishing electrolyte was getting
09:59:09 15 inside the apex of the filter where we have the snare tip
16 that's welded on and it was eating away the welds.

17 So what we introduced was a new failure mode where we
18 compromised the weld. So once we saw that, we stopped that
19 project. We could not terminally electropolish that
09:59:29 20 particular filter.

21 Q And did the Platinum filter as you described it, did it
22 make it out of the concept phase?

23 A No, it did not.

24 Q And so did Bard decide to pursue other efforts to try to
09:59:43 25 employ electropolishing in its filters?

DIRECT EXAMINATION - MICHAEL RANDALL

09:59:46 1 A Yeah. It was at that time where we were then kicked off
2 the Eclipse project. And --

3 Q Let me interrupt you for just a minute, Mr. Randall. I'm
4 sorry.

09:59:55 5 MR. ROGERS: Can we take this down and go back to the
6 timeline, 8482, please.

7 BY MR. ROGERS:

8 Q Okay. So --

9 MR. ROGERS: And can you connect up the Platinum and
10:00:06 10 the Eclipse work there?

11 THE COURT: Can you display that, Traci.

12 MR. ROGERS: I'm sorry. Yeah, can we display that.

13 BY MR. ROGERS:

14 Q Okay. So when did Bard end the Platinum project and start
10:00:22 15 the Eclipse project?

16 A It was the August 2009 time frame.

17 Q And can you tell the jury what was going to be different
18 about the work you were going to do to develop the Eclipse
19 filter versus what you had already done with the Platinum
10:00:36 20 filter?

21 A Yeah. So once we realized we couldn't terminally
22 electropolish the entire filter, what we decided to do is
23 let's take a shot at electropolishing every single component.
24 So there's 12 wires that make up six arms, six legs, and then
10:00:55 25 there's also a tip. So we were going to electropolish every

DIRECT EXAMINATION - MICHAEL RANDALL

1 single component separately and then assemble it together.

2 MR. ROGERS: Can we take this down and pull up
3 Exhibit 8575.

4 Your Honor, this is admitted. May we publish?

5 THE COURTROOM DEPUTY: Yes, it's admitted.

6 THE COURT: Yes, you may.

7 BY MR. ROGERS:

8 Q Okay. Mr. Randall, what is this document?

9 A This is the cyclic fatigue testing of electropolished
10 vail filter wire. Vail is the internal code name for the
11 project which became Eclipse.

12 Q And so was this the first step in order to try and start
13 the testing process for the Eclipse filter?

14 A Yeah. This is one of the -- the first steps to really
15 see is electropolish going to go help out. So that's why we
16 conducted this test.

17 Q Okay.

18 MR. ROGERS: So let's go to page 5.

19 And up at the top there's a table there. Would you
20 mind pulling that out, please.

21 BY MR. ROGERS:

22 Q And just before we move into the table, can you describe
23 for us generally what this test was doing, how it worked.

24 A Yeah. So this was a cyclic fatigue test. So essentially
25 we took wire, and imagine doing a bend test where we can push

DIRECT EXAMINATION - MICHAEL RANDALL

10:02:33 1 it up and down and cause the wire to basically flex. Right.
2 And we did this -- we did these deflections to be -- I mean,
3 they were really challenging deflections, not like the
4 deflections you see in IVC.

10:02:50 5 And the reason you do this is because you want to
6 force a failure fast. That way you can then come back and do
7 your improvement and see how does that one fail. So it was a
8 test specifically designed to make the product fail as fast as
9 possible.

10:03:07 10 Q In the table that we see, what were the two steps of wires
11 you were testing.

12 A It was the G2X wire on electropolishing and the Eclipse
13 electropolished filter wire.

14 Q And is the document that we see now, is this the protocol
10:03:23 15 for the wire testing?

16 A Yes, it is.

17 Q Okay.

18 MR. ROGERS: So can we move that down, please, and
19 pull up Exhibit 8574.

10:03:32 20 And, Your Honor, may we publish? This has been
21 admitted.

22 THE COURTROOM DEPUTY: Yes.

23 THE COURT: Yes.

24 BY MR. ROGERS:

10:03:47 25 Q And, Mr. Randall, are these the -- the document that

DIRECT EXAMINATION - MICHAEL RANDALL

10:03:50 1 reports the tests of the wire fatigue tests that you were
2 describing earlier that reports results --

3 A Yes, it is. It's the test report.

4 MR. ROGERS: And so let's go to page 10.

10:04:04 5 And how about pull out those two tables up there.

6 BY MR. ROGERS:

7 Q And, so, Mr. Randall, if you would, how about explain to
8 us what the results of the test were.

9 A Yeah. So if you look at this top table and you look at
10:04:20 10 the third column, which says "mean cycles," that's
11 essentially the number of cycles it took to make that wire
12 fail given those really high forces that we put on high
13 deflections. And what it showed is the G2X on average 194,
14 and then Vail or Eclipse, 345 to get that wire to fracture.

10:04:49 15 Q And so how about Table 8 just below there?

16 A Yeah. So mean cycles to fracture resulted in a
17 77.4 percent increase. If you look at the mean.

18 Q So how did the electropolished wire stack up against the
19 nonelectropolished wire?

10:05:09 20 A It was 77.4 percent better in fatigue performance with
21 these testing parameters here.

22 Q So let's continue to move through some of the other
23 testing that you did.

24 MR. ROGERS: And let's go now to Exhibit 8546.

25

DIRECT EXAMINATION - MICHAEL RANDALL

10:05:31 1 BY MR. ROGERS:

2 Q And, Mr. Randall, can you see that on your screen?

3 A Yes, I can.

4 Q And just in general, can you just tell us what it is?

10:05:45 5 A This is a memo documenting the rotary beam fatigue of
6 Nitinol wire. So I believe there was some nonelectropolished
7 and also electropolished wire that was tested. And it was
8 tested via a rotary beam, so.

9 Q Let me stop you for just a second.

10:06:06 10 Was this document kept in the ordinary business at
11 Bard?

12 A Was it kept -- I don't understand.

13 Q I'm sorry. Was this document maintained and kept in the
14 ordinary course of business at C.R. Bard?

10:06:20 15 A Yes.

16 Q And was it made at or near the time that Bard did this
17 test?

18 A Yes.

19 Q And was it Bard's regular practice in order to create this
10:06:28 20 document and maintain the document?

21 A Yes.

22 MR. ROGERS: Your Honor, I would now move 8546 into
23 evidence.

24 MR. STOLLER: Your Honor, we object under 803(6). I
10:06:40 25 don't believe under 602 this witness has the foundation to

DIRECT EXAMINATION - MICHAEL RANDALL

10:06:42 1 testify about the matters he just described. And I'm happy to
2 address it more fully.

3 THE COURT: Would you lay additional foundation,
4 please, on the witness's knowledge.

10:06:53 5 MR. ROGERS: Sure.

6 BY MR. ROGERS:

7 Q And, Mr. Randall, do you have personal knowledge of this
8 document?

9 A Yes, I do.

10:06:59 10 Q And would you have been involved in the creation of this
11 document?

12 A Yes. I basically worked with Andrzej when he put this
13 together.

14 Q And can you attest here today that this document was
10:07:10 15 maintained in the ordinary course of Bard's business?

16 A Yes.

17 MR. ROGERS: Your Honor, I would move it into
18 evidence.

19 MR. STOLLER: Your Honor, under 803(6)(E), we
10:07:20 20 challenge that they're not able to show that the source of the
21 information or method or circumstances of the preparation
22 indicate that there's a lack of trustworthiness with respect
23 to this document.

24 THE COURT: Well, that's your burden.

10:07:32 25 MR. STOLLER: I understand. Can I voir dire the

VOIR DIRE EXAMINATION - MICHAEL RANDALL

witness?

THE COURT: Sure.

MR. STOLLER: I'll do it from here.

V O I R D I R E E X A M I N A T I O N

BY MR. STOLLER:

Q Mr. Randall, are you the author of this document?

A No. Andrzej is.

Q And if you look on the first page, it has a TD number at the very top; correct?

A Correct.

Q And there are question marks at the end of that?

A Correct.

Q Indicating it is not done; you don't know what number this has been assigned. Correct?

A Correct. This draft here.

Q This is a draft document; correct?

A This is.

Q And if we look under the "from," there is no indication of who it is from; correct?

A Correct.

Q And if we go to the last page of the document it's unsigned.

MR. STOLLER: Could we go to the last page, please, I'm sorry, the signature page.

DIRECT EXAMINATION - MICHAEL RANDALL

10:08:16 1 BY MR. STOLLER:

2 Q Unsigned; correct?

3 A Correct.

4 Q You have processes in place at Bard for the review and
10:08:25 5 finalization of test reports. True?

6 A True.

7 Q They're reviewed by people who sign off on them. True?

8 A Correct.

9 Q Okay. And this report does not have any have those
10:08:35 10 indicia that it went through that process. True?

11 A True.

12 MR. STOLLER: No further questions, Your Honor.

13 THE COURT: Anything further, Mr. Rogers?

14 D I R E C T E X A M I N A T I O N (RESUMED)

10:08:43 15 BY MR. ROGERS:

16 Q Mr. Randall, is this the only document that you're aware
17 of that would relate to the rotary beam test that you were
18 describing?

19 A Yeah, this is the only one that I know of.

10:08:55 20 THE COURT: All right. Let's approach for a minute
21 Counsel.

22 Feel free to stand up, ladies and gentlemen.

23 (Bench conference as follows:)

24 THE COURT: Mr. Stoller, if he testifies he was
10:09:15 25 involved, he knows it was created, he knows it was related to

DIRECT EXAMINATION - MICHAEL RANDALL

1 a test that he was involved in, and it was kept in the
2 ordinary course of business, what's the lack of
3 trustworthiness for business records purposes?

4 MR. STOLLER: Your Honor, there's a couple of
5 problems I have with this document.

6 One is that we've not objected to the entry of tests
7 generally where it's been through the process he just
8 described, which is that they go through that process to
9 ensure that it is accurate, which is one of the indicia of
10 trustworthiness, why business records are business records and
11 they're allowed to come in --

12 THE COURT: Let me interrupt you. That's not
13 correct, in my view. There is no requirement in the business
14 records exception that there be some internal trustworthiness
15 evaluation that there is for purposes of a test result. It's
16 a different question. It's trustworthiness for purposes of
17 whether or not it's a business record.

18 MR. STOLLER: I'm not disagreeing with Your Honor.
19 I'm saying that the other elements of the business record
20 exception are to meet that indicia of trustworthiness, which
21 is why the exception in (E) exists, which is that if I can
22 come in -- if they can establish (A) through (D), which would
23 get them past the preliminary hurdle we have with most hearsay
24 documents, right, which is a --

25 THE COURT: Right.

DIRECT EXAMINATION - MICHAEL RANDALL

10:10:25 1 MR. STOLLER: -- concern about lack of
2 trustworthiness, I can come in and challenge it and
3 demonstrate it doesn't have proper indicia of it.

4 My point being their processes, their internal
10:10:35 5 processes that get them to this is a regularly kept
6 business -- regularly kept record in the course of their
7 business --

8 THE COURT: Pardon me for interrupting.

9 That's where I'm having a problem. I don't think
10:10:48 10 their internal processes for validating test results are
11 internal processes for determining whether or not this is a
12 business record. You seem to be conflating the two.

13 MR. STOLLER: I am, and intentionally so, and I don't
14 mean to be conflating them. I believe they're one in the
10:11:01 15 same, which is, is you have their process of -- I don't
16 believe this is a regularly maintained business record. It's
17 not relating -- again, it is not a final report. Their
18 regularly maintained business records are consistently final
19 reports that have been through this process.

10:11:15 20 This is a document that is pulled -- and I will tell
21 you, Your Honor, I went through -- after they identified it, I
22 went through -- this is the only version. There's no final
23 version anywhere. There is no metadata associated with this
24 particular piece of -- this particular exhibit that I can find
10:11:32 25 anywhere. It's not clear where it came from.

DIRECT EXAMINATION - MICHAEL RANDALL

10:11:34 1 It's not part of this project, the Eclipse filter
2 we're talking about here. It has a number associated with an
3 entirely different project. So where it came -- it doesn't --
4 I don't think that they've established that it meets the -- it
10:11:50 5 is a regularly maintained business record in the sense that it
6 is kept as part of -- and I've distinguished from they have an
7 obligation for each of these devices to maintain a design
8 history file, as you know and you've heard.

9 This is not part of the design history file of any of
10:12:04 10 the devices that went to market. It's a record that was
11 gathered from somewhere. And sitting here, not every record,
12 just because it's maintained, is a business record just
13 because it is somewhere in the bowels. It has to meet those
14 indicia that are part of (A) through (D) that it is such that
10:12:18 15 we can -- you can -- you can offer it in evidence over a
16 hearsay objection.

17 And I think for the reasons we've articulated, this
18 particular document has not been through the processes that it
19 gets to those files.

10:12:30 20 THE COURT: Okay. Did you have more to say?

21 MR. STOLLER: I do not, Your Honor.

22 MR. ROGERS: Your Honor, it is a draft, but I think
23 we've established it is maintained in the ordinary course of
24 business at Bard. It's the only document Bard has been able
10:12:44 25 to locate for this particular test.

DIRECT EXAMINATION - MICHAEL RANDALL

10:12:45 1 We've admitted scads of documents in this case that
2 are drafts. And if we're going to enter a standard where
3 draft documents are not considered regularly kept business
4 records, I think that could be an interesting new twist on
10:13:03 5 things.

6 It's there in the files at Bard. And the witness has
7 testified that it's maintained in the ordinary course.

8 THE COURT: All right. Any other points?

9 MR. STOLLER: No, Your Honor.

10:13:13 10 THE COURT: Okay. My conclusion is that Mr. --
11 what's his name?

12 MR. ROGERS: Randall.

13 THE COURT: -- Mr. Randall is a qualified witness for
14 purposes of 803(6)(D). He has testified that the elements of
10:13:29 15 803(6)(A), (B), and (C) exist. The jury can choose to believe
16 or disbelieve him. But I think that's enough to establish
17 those four elements if the jury accepts it. That's the
18 standard for authentication of admission.

19 The question then is whether the points you've made,
10:13:45 20 Mr. Stoller, that it wasn't completed or made a final version
21 and put into the regular testing files of Bard makes the
22 document untrustworthy for purposes of the business records
23 exception, and I do not think it does. I think he has laid
24 sufficient foundation for it to be admitted. And everything
10:14:05 25 you just pointed out goes to the weight, not the

DIRECT EXAMINATION - MICHAEL RANDALL

10:14:09 1 admissibility.

2 MR. STOLLER: I'll cross-examine him on it,
3 Your Honor.

4 THE COURT: So I will overrule the objection.

10:14:14 5 (Bench conference concludes.)

6 THE COURT: Thank you, ladies and gentlemen.

7 The objection is overruled, and 8546 is admitted.

8 (Exhibit 8546 admitted.)

9 MR. ROGERS: Thank you, Your Honor.

10:14:27 10 May we publish the document?

11 THE COURT: Yes.

12 BY MR. ROGERS:

13 Q And, Mr. Randall, if you would, I think at one point you
14 were about to tell the jury about this particular test, the
10:14:41 15 rotary beam test, and I stopped you. And so let me ask you
16 again to tell us about that.

17 A Yeah. So rotary beam fatigue, to explain the test, it's
18 a kind of interesting test. So if you take a wire, okay, if
19 I have a wire and if I bend it, this outside surface is in
10:15:02 20 tension. The inner surface is in compression. Right?

21 So now if I hold the wire, and, say, I have some
22 pulley here and I have this radius made, on this end I hook
23 up, say, like a drill. On this end I have a free spindle.

24 And I rotate the wire with this drill so the wire is just

10:15:21 25 constantly rotating. Then the outside surface/inside surface

DIRECT EXAMINATION - MICHAEL RANDALL

10:15:26 1 is alternating back and forth. So that's why it is called
2 rotary beam fatigue. So I'm flexing it in tension,
3 compression, tension, compression.

4 And then the pulley size that I use, I use different
10:15:40 5 size pulleys. The different size pulleys account for the
6 different strains I put on the wire. So I'll run it at a
7 particular strain and I'll run it for certain amount of cycles
8 and see how many breaks.

9 Then I change out the pulley to increase strain, see
10:15:58 10 how many breaks. And then I increase it again and increase it
11 again. And what I'm ultimately looking for is the endurance
12 limit of the wire. So basically the maximum strain limit I
13 can induce in that wire.

14 And that's the purpose of a rotary beam fatigue test.

10:16:17 15 Q And you mentioned that you're looking at the endurance
16 limit. Can you tell us a little bit more what that means?

17 A So endurance limit, it's essentially -- for Nitinol based
18 products, the product, how fatigue resistant the product is,
19 you deal with strain. How much can I basically bend it.

10:16:37 20 Strain it. Strain is just bending it.

21 So the more I can strain it, if it can take more
22 strain before it fractures, that means you improve the fatigue
23 performance. If it takes less strain, meaning I can only bend
24 it less, cycle it less, and then it fractures, that means it
10:16:56 25 is reduced fatigue limit. So it's a material property that

DIRECT EXAMINATION - MICHAEL RANDALL

10:17:01 1 I'm looking at right now.

2 MR. ROGERS: And, Scott, would you pull out the table
3 that's at the bottom of the page.

4 Thank you.

10:17:08 5 BY MR. ROGERS:

6 Q And, Mr. Randall, if you would, tell us what are the wires
7 that you were testing?

8 A Looks like there's some Johnson Matthey control wire,
9 which I believe is probably the regular G2, G2X type of
10:17:28 10 wires. Then we have some Eclipse wires that were tested in
11 different diameters.

12 MR. ROGERS: So let's go to page 3 and look at the
13 conclusion. And would you pull that out.

14 BY MR. ROGERS:

10:17:44 15 Q And, so, Mr. Randall, tell us what the results of this
16 test were.

17 A Yeah. So this says all the tested wires can be
18 considered equivalent or better than the control wire at
19 .65 percent strain level.

10:18:00 20 MR. ROGERS: And if you would, would you take that
21 down, Scott, and I believe there's some additional information
22 in the preceding paragraph. Would you pull out that
23 paragraph, please.

24 BY MR. ROGERS:

10:18:08 25 Q And, Mr. Randall, can you explain this to us.

DIRECT EXAMINATION - MICHAEL RANDALL

10:18:13 1 A Yeah. If you go to --

2 Q You want that last sentence highlighted?

3 A It's the last sentence that you would want to highlight.

4 Q Okay.

10:18:30 5 A Yeah. And since no actual data exists due to the limited
6 number of samples available for testing, the endurance limit
7 of the RD08, that's the G2 one, can be conservatively
8 estimated at .65 percent strain. And then the endurance
9 limit of electropolished wires can be conservatively
10:18:53 10 estimated at .85 percent strain.

11 So the improvement, the regular unelectropolished
12 wire, you can flex it .65, .65 percent strain. And then
13 when -- and over and over again and it should be fine. Right?
14 If you go past that, then you'll run into fracture.

10:19:18 15 The electropolished wire can be cyclic fatigue and
16 strain more than that to go .85. And if you go past that,
17 that's when you can run into fracture.

18 Q And so if you were to express the -- how would you compare
19 the .65 percent to the .85 percent, in a percentage how those
10:19:43 20 two things compare to each other from a percentage performance
21 standpoint, what would that be?

22 A So the percent increase in improvement of going to
23 electropolishing results in 30 percent. So 30 percent
24 improvement in the fatigue endurance limit of the wire.

10:20:07 25 MR. ROGERS: Okay. Would you pull that down, please,

DIRECT EXAMINATION - MICHAEL RANDALL

1 Scott, and let's pull up Exhibit 8373.

2 Your Honor, this has been admitted. May we publish?

3 THE COURTROOM DEPUTY: Yes.

4 THE COURT: Yes, you may.

5 BY MR. ROGERS:

6 Q Mr. Randall, can you tell us what this document is?

7 A Yes. This is the DV&V Vail filter arm fatigue
8 evaluation.

9 Q And we looked at one arm fatigue test already. And so
10 it -- what does DV&V stand for?

11 A Design verification and validation.

12 Q And, Mr. Randall, how does this test differ from the one
13 that we looked at previously?

14 A The one that we looked at previously, we just took the
15 wire itself and flexed it. This particular test here we
16 built whole filters out of and we tested the filter arm in
17 it. So we made a filter, went and saw all of the processes
18 of forming, heat setting, shape, and so forth, and then we
19 fatigued it.

20 Q And did you -- can you describe how you manipulated the
21 arm in order to test it?

22 A Yeah. So like I said, you know, with these tests here
23 you're trying to drive a failure soon. Right? And then you
24 want to see how it compares to the change you made. So if
25 the arm naturally sits like this, what we did is we went to

DIRECT EXAMINATION - MICHAEL RANDALL

10:21:49 1 kind of a saluting arm where we bent it up. Up, you know,
2 something that normally it would not see. And we did this
3 type of flex test on it because we wanted to accelerate the
4 failure. And then we test the change and see how it
10:22:06 5 performs.

6 MR. ROGERS: Okay. Scott, would you take that down
7 and pull up 8359.

8 Your Honor, this has been admitted. May we publish?

9 THE COURT: Yes.

10:22:27 10 BY MR. ROGERS:

11 Q Mr. Randall, are these the reports that provided the
12 results of the DV&V arm fatigue testing you just described?

13 A Yes, it is.

14 MR. ROGERS: And can we go to page 9, please.

10:22:43 15 And let's pull out the -- I guess starting with the
16 box and whisker plot down to the chart that's there at the
17 bottom.

18 BY MR. ROGERS:

19 Q And so if you would, Mr. Randall, can you tell us, please,
10:22:57 20 what the results of this test were?

21 A Yeah. So I would look at Table 7. And I would look at
22 the third column, which says "mean cycles." So that's the
23 mean cycles to failure.

24 And what it shows is that the Vail took 719 was the
10:23:18 25 mean, and then the G2X, which is a nonelectropolished wire,

DIRECT EXAMINATION - MICHAEL RANDALL

1 would take 440 cycles. So it showed an improvement.

2 Q So did the electropolished wire appear to have more
3 fracture resistance than the previous wire?

4 A Yes, it does.

5 MR. ROGERS: Okay. Let's take that down and go to
6 document 8368.

7 And, Your Honor, I believe this is in evidence. May
8 we publish?

9 THE COURT: Yes.

10 BY MR. ROGERS:

11 Q And, Mr. Randall, if you would, could you explain what
12 this test is.

13 A Yeah. So this is the DV&V flat plate fatigue and
14 corrosion examination of the filter. This is also an
15 accelerated fatigue test, but unlike the previous tests that
16 were shown, this is not a test to failure. This is a test
17 that you have to pass. And this is one of the tests that is
18 required by the FDA agency when submitting for approval.

19 And the way this test works is, remember I said that
20 the vena cava is oval shaped? So we had to utilize a test,
21 and we call it flat plate because we took a tube, because a
22 tube -- you don't get tubes extruded ovally, typically come
23 round. But then we put them between two flat plates and you
24 smash it so it makes an oval, and then you load the filters in
25 and then you deflect it and then come back and forth. So you

DIRECT EXAMINATION - MICHAEL RANDALL

10:24:53 1 have an oval, a smaller oval. And that is why it's called
2 flat plate fatigue. And you do it for a number of cycles and
3 it has to pass.

4 MR. ROGERS: Let's go to page 7 of the document. And
10:25:05 5 there's a section there called "Test Duration 12.3." Would
6 you pull that out.

7 BY MR. ROGERS:

8 Q And you mentioned the number of cycles. And, Mr. Randall,
9 can you explain to the jury how you determined how many cycles
10:25:21 10 the filters would be put through for this test?

11 A Yeah. So based on guidance documents, standards in the
12 industry, the devices need to be accelerated age fatigue for
13 ten years equivalent. And for this particular test here, we
14 were trying to mimic Valsalva maneuvers. Remember, like I
10:25:46 15 said, if you bear down or if you cough, that can cause that
16 major deflection.

17 So, you know, we wanted to make it challenging. So
18 one of the frequencies that -- the frequency we decided to go
19 with is someone who has coughing frequencies of 43 coughs per
10:26:09 20 hour. And that is someone who is really, really sick and has
21 some respiratory issues.

22 So 43 coughs per hour, and if you take hours, you
23 know, 24 hours a day, how many days, 365 a year, you wind up
24 with -- if you can highlight the 3,700- -- it's the
10:26:39 25 second-to-the-last sentence to the left.

DIRECT EXAMINATION - MICHAEL RANDALL

10:26:42 1 Q Second to last line?

2 A Yeah. Right there.

3 So that 3,766,800 cycles represents ten years of
4 coughing 43 times per hour over 24 hours. You're not even
10:27:04 5 sleeping. So, like, I'm assuming you're coughing 24 hours in
6 your sleep.

7 So it's probably more than ten years. But then we
8 also round it up to 4 million just to have a round number.
9 And we had the device be deflected for these really -- you
10:27:25 10 know, the diaphragmatic type of deflections, and it had to
11 meet this requirement.

12 Q And how does this test work so that you are using the flat
13 plates to squeeze the filter for an equivalent of ten years?

14 A Yeah. So, you know, it's hard to conduct accelerated
10:27:44 15 fatigue tests because the actual apparatus that's causing the
16 deflection could cause what we call fretting fatigue.

17 Basically, if I push something so fast it can't keep up.

18 This test was probably ran at 40 hertz, which means 40
19 deflections per second, and essentially it was taken at oval
10:28:08 20 with the flat plate and going to a smaller one per the
21 deflections that were defined that represented diaphragmatic
22 movement and pressures.

23 MR. ROGERS: Okay. Let's take that down and go to
24 document 8358.

10:28:25 25 Your Honor, this has been admitted. May we publish?

DIRECT EXAMINATION - MICHAEL RANDALL

10:28:29 1 THE COURT: Yes.

2 BY MR. ROGERS:

3 Q And, Mr. Randall, are these the document that reports on
4 the results of the flat plate testing?

10:28:37 5 A Yes, it is.

6 MR. ROGERS: And if we could go to page 6 of the
7 document, please.

8 BY MR. ROGERS:

9 Q And under the "Results" section, can you tell us what the
10:28:49 10 results were, please.

11 A Yeah. So November of 2009, all the filters were
12 successfully pulsated to 4 million cycles, which is
13 equivalent to ten years. Probably greater than ten years.

14 Q So all the filters that were subjected to the flat plate
10:29:12 15 testing passed the test?

16 A Yes.

17 Q And if you would, let's move on down to 11.2. And this
18 says "Examination of Corrosion Resistance." What does that
19 mean?

10:29:22 20 A In the guidance doc, there needs to be an examination of
21 the filter surface to make sure we do not see any things like
22 rust or anything like it's corroding. There was an
23 examination done and there was no evidence of corrosion
24 present.

10:29:40 25 THE COURT: We're going to break at this point,

DIRECT EXAMINATION - MICHAEL RANDALL

10:29:41 1 Mr. Rogers.

2 We will resume, ladies and gentlemen, at 10:45.

3 (The jury exited the courtroom at 10:29.)

4 THE COURT: Counsel, the three exhibits that
10:30:12 5 plaintiff's counsel gave me related to Recovery filter related
6 deaths were 1032, 1722, and 2148.

7 I don't know if defense counsel have had a chance to
8 look at those three?

9 MR. NORTH: We have, Your Honor.

10:30:29 10 THE COURT: Do you have comments on those --

11 MR. NORTH: In addition to the previous arguments we
12 made, we believe that the introduction of these three
13 documents would just trigger an enormous amount of prejudice
14 at this time, particularly on this last day of trial. It's
10:30:47 15 going to give the appearance, when the jury sees those three
16 documents, that they're admitted, that the defense has been
17 hiding something. We think it's a level of prejudice that we
18 cannot recover from. And that these three documents singly or
19 together are overkill, given the very measured testimony of
10:31:08 20 Dr. DeFord, and the plaintiff's clear solicitation in that
21 deposition that he -- there had been pulmonary embolism
22 deaths. And that is something they designated and was put in.

23 Alternatively, and we're not suggesting this as a
24 compromise, Your Honor, because we do not believe the door has
10:31:25 25 been opened, and to open it at this point is going to create

DIRECT EXAMINATION - MICHAEL RANDALL

10:31:29 1 insurmountable 403 prejudice --

2 THE COURT: Before you go there for a minute,
3 Mr. North, the language that you identified from the DeFord
4 deposition, it's in a question that was asked --

10:31:43 5 MR. NORTH: Right.

6 THE COURT: -- doesn't have anything to do with
7 filter deaths. It says: So when Bard was weighing, do we
8 take this off the market, do we keep it on the market, and
9 you're telling me that Bard decided, well we need to go save
10:31:59 10 all these patients from these massive pulmonary embolisms that
11 are killing people all over the country, you had a device that
12 was already doing that; right? You had the Simon Nitinol.

13 So it's not referring to filter deaths. It's saying
14 Bard was going to save people from pulmonary embolism death.
10:32:19 15 That's the way I'm reading the question on page 41.

16 And the point is --

17 MR. NORTH: Your Honor, you are correct. I did
18 misread that reference to that. I apologize.

19 THE COURT: I wanted to make sure --

10:32:38 20 MR. NORTH: I believe there were other sections where
21 they're bringing up serious migration incidents without the
22 word death.

23 But if I could lastly say as an alternative -- and,
24 again, we think the 403 prejudice is there for all of them,
10:32:50 25 but the alternative would be to only allow them to present the

DIRECT EXAMINATION - MICHAEL RANDALL

10:32:54 1 health hazard evaluation that provides a very sort of
2 scientific overview of the adverse events. And if they are
3 allowed to do that, Your Honor, we have a couple more
4 documents that we would have put in with two of our previous
10:33:10 5 witnesses that we would then like to introduce in rebuttal.

6 THE COURT: What are those documents?

7 MR. NORTH: One would be the Dear Colleague letter,
8 that's Exhibit 5247, where Bard specifically sent out a letter
9 that was reviewed by the FDA to doctors advising them of these
10:33:31 10 deaths. I think it's important that we be allowed to show we
11 warned about that and sent -- and made some effort to some
12 warn people --

13 THE COURT: Is that the letter about deaths in
14 morbidly obese patients?

10:33:43 15 MR. NORTH: Yes, Your Honor.

16 THE COURT: All right.

17 MR. NORTH: And the second one would be an FDA
18 contact report that came in at the last trial, that's
19 Exhibit 5239. That is a contact report that if this issue had
10:33:52 20 been part of the trial beforehand we would have discussed with
21 Ms. Shari Allen, it was admitted in Booker, she authored this,
22 and it memorializes her conversations with the FDA about much
23 of this data they're trying to get in.

24 THE COURT: Okay. Any comments from plaintiff's
10:34:11 25 counsel?

DIRECT EXAMINATION - MICHAEL RANDALL

10:34:14 1 Mr. Clark.

2 MR. CLARK: Your Honor, we don't think that these --
3 let me go to the podium -- three documents are overkill.
4 Obviously there are a number of documents. We tried to select
10:34:28 5 ones that we thought were representative of the chronology in
6 that snapshot of the story. I think that all three would be
7 appropriate and could be dealt with reasonably quickly.

8 So, again, and just to go back to this idea that this
9 was not a door we opened. We did not present Dr. DeFord. We
10:34:47 10 did not -- we had some designations in there, but that was in
11 response to what the defendants had put into evidence. So we
12 feel like we need to be able to tell the other side of the
13 story.

14 THE COURT: Okay. I will keep thinking about this.

10:34:59 15 Thank you, all.

16 MR. NORTH: Your Honor, should we have Mr. Carr
17 remain here still?

18 THE COURT: Please.

19 MR. NORTH: Thank you.

20 (Recess taken from 10:35 to 10:52. Proceedings resumed
21 in open court outside the presence of the jury.)

22 THE COURT: Thank you. Please be seated.

23 All right, Counsel, let me give you my decision on
24 this issue.

10:53:06 25 I've looked at the three exhibits the defendants

DIRECT EXAMINATION - MICHAEL RANDALL

10:53:09 1 proposed. I have reviewed again the DeFord excerpts and I've
2 reviewed my notes of the DeFord excerpts.

3 This is where I come down on the issue.

4 I continue to be of the view that deaths related to
10:53:25 5 the use of the Recovery filter are marginally relevant at best
6 in this case because of the fact that cephalad migration and
7 deaths related to cephalad migration largely stopped when the
8 Recovery filter ended, and were not present in any meaningful
9 degree in the G2, G2X, or the Eclipse.

10:53:51 10 The possibility that the deaths should have caused
11 Bard to recall the Recovery and therefore it wouldn't have
12 been the predicate for the G2, in my view, isn't a relevant
13 point in this case for reasons I stated in the order last
14 night.

10:54:06 15 However, I do agree that the complaint history with
16 the Recovery filter is a relevant point in the history of this
17 whole line of filters and is relevant for the jury to
18 understand. I have not felt that the death component of that,
19 which, again, was largely eliminated with the G2, was
10:54:26 20 sufficiently relevant that it survived a 403 analysis. I
21 thought the risk of unfair prejudice substantially outweighed
22 that limited relevance.

23 The question now is whether the testimony of
24 Dr. DeFord changes that balance.

10:54:41 25 What Dr. DeFord said specifically was in response to

DIRECT EXAMINATION - MICHAEL RANDALL

10:54:45 1 a question about whether, if Bard put patient safety at the
2 forefront, it should have stepped back from selling the
3 Recovery. In other words, pull it off the market, I think is
4 what the question was. And his answer was that he disagreed
10:55:06 5 because the evaluation at the time was, and now I'm quoting,
6 "That this technology was saving many more lives than it was
7 unable to save. And by -- and if we took it off the market
8 and did not have that technology available, then that would
9 further increase the risk to patients versus decrease the risk
10:55:25 10 to patients." That's the end of the quote.

11 I do believe that for the jury to accurately evaluate
12 that decision by Bard with respect to the Recovery filter, it
13 would be relevant for them to know there were reported deaths
14 related to the Recovery filter. If that were the central
10:55:48 15 issue in the case, it would be absolutely critical evidence.
16 But the DeFord testimony does, in my view, suggest that
17 knowledge of death would better allow the jury to evaluate the
18 decision made in 2004 and 2005 as to whether or not the
19 Recovery should not be sold.

10:56:05 20 So the question then becomes whether that increased
21 relevancy from Dr. DeFord's testimony changes the 403 balance
22 that I've been reaching a number of times throughout the case.

23 I think reasonable jurors -- jurists could come to
24 different conclusions on this. It's a close question, in my
10:56:28 25 view.

DIRECT EXAMINATION - MICHAEL RANDALL

10:56:28 1 But I continue to believe that death evidence
2 presents a risk of unfair prejudice when it's by a method of
3 migration that was not present in the G2, G2X, or Eclipse
4 filters, and when it occurred five and six years before the
10:56:44 5 Eclipse filter that was implanted in this case.

6 And whether or not Bard struck the right balance in
7 dealing with Recovery complications at that point in time,
8 although a relevant point on the history, is a remote relevant
9 point on the history. And the jury's ability to evaluate that
10:57:05 10 specific point, in my view, with this additional death
11 evidence does not make that evidence so relevant that I come
12 to a different conclusion on the 403 balancing. I continue to
13 think that the death evidence from a method of migration that
14 no longer existed, a filter that no longer existed, which is
10:57:28 15 likely to elicit an emotional response, creates a danger of
16 unfair prejudice that substantially outweighs the probative
17 value of the evidence, even with Dr. DeFord's additional
18 answer to that question.

19 That's my best judgment on the question.

10:57:44 20 So I'm going to continue to stand by the decision
21 I've been making, that the cephalad migration death evidence
22 should not be admitted.

23 That means I think you can have Dr. -- pardon me,
24 Mr. Carr excused.

10:58:01 25 MR. NORTH: Thank you, Your Honor.

DIRECT EXAMINATION - MICHAEL RANDALL

10:58:02 1 THE COURT: We'll continue with Mr. Randall.

2 (The jury entered the courtroom.)

3 THE COURT: All right. Thank you, ladies and
4 gentlemen, for your patience. We're late getting you back in.

10:59:21 5 We were resolving an evidence issue that we needed to resolve
6 before we finished the evidence.

7 Please be seated.

8 Mr. Rogers, you may continue.

9 MR. ROGERS: Thank you, Your Honor.

10:59:30 10 Your Honor, may I we publish 8358, which is in
11 evidence and was on the screen?

12 THE COURT: Yes, you may.

13 MR. ROGERS: Thank you.

14 BY MR. ROGERS:

10:59:38 15 Q Mr. Randall, before we took our morning break, you were
16 telling us about the portion of this document about corrosion
17 testing.

18 MR. ROGERS: And if we could pull that back out.

19 11.2. Or, excuse me, not corrosion testing, corrosion
10:59:53 20 resistance. I'm sorry. And -- thank you. Well, almost
21 there.

22 All right. Perfect.

23 BY MR. ROGERS:

24 Q And, Mr. Randall, in this particular paragraph there's a
11:00:05 25 couple of references to 40x. Could you explain to the jury

DIRECT EXAMINATION - MICHAEL RANDALL

11:00:08 1 what that is?

2 A That is the magnification that was used on the microscope

3 to evaluate these.

4 Q And is that a scanning electron microscope or something --

11:00:21 5 A Just a regular microscope.

6 Q And based on the review with the microscope, did Bard see

7 any evidence of corrosion in the tested filters?

8 A No. No evidence of corrosion.

9 Q All right.

11:00:36 10 MR. ROGERS: Let's take that down and go to the next

11 paragraph, the 11.3.

12 BY MR. ROGERS:

13 Q And, Mr. Randall, this says "Examination of weld strength

14 following cycling." Can you tell us what that means?

11:00:49 15 A Yeah. So after the fatigue testing, what we then did is

16 we attached a five-pound load onto each filter appendage. So

17 each arm and leg had to hold five pounds and not come off.

18 And it successfully passed that.

19 Q Mr. Randall, I think you told us this earlier, but did all

11:01:13 20 12 of this Eclipse filters pass this test?

21 A Yes, they did.

22 Q And so what did that mean?

23 A That meant that it passed the results to simulate ten

24 years of implant life. Met the requirements for the DV&V

11:01:31 25 testing which we would use for this submission.

DIRECT EXAMINATION - MICHAEL RANDALL

11:01:33 1 Q And after all of these various fatigue-related tests were
2 completed, what did Bard conclude regarding the Eclipse filter
3 and whether it had the potential to improve fatigue once it
4 was used in patients?

11:01:47 5 A Yeah, so after the various fatigue testing and conducting
6 the flat plate, we concluded that electropolishing would, in
7 fact, help improve the fatigue resistance of the vena cava
8 filter.

9 Q And did any of the electropolishing that was added to --
11:02:11 10 with the Eclipse filter, would that help improve migration,
11 tilt, or perforation?

12 A No, it would not.

13 Q And did Bard have other projects that were underway to try
14 to address those issues?

11:02:24 15 A Yes, we did.

16 MR. ROGERS: Scott, if you would, would you take that
17 down and bring back 8482.

18 And, Your Honor, this is the demonstrative. May we
19 publish?

11:02:37 20 THE COURT: Yes.

21 BY MR. ROGERS:

22 Q Mr. Randall, we talked now about the Platinum and the
23 Eclipse projects, and those were the ones that related to
24 electropolishing; is that right?

11:02:46 25 A Correct.

DIRECT EXAMINATION - MICHAEL RANDALL

11:02:47 1 Q And let's talk about some of those other projects. We
2 have here also on the screen the Meridian project. And can
3 you tell us when that began.

4 A Meridian began in February of 2009.

11:03:01 5 Q And how about the Denali project, when did it begin?

6 A August 2009.

7 Q So at some point around 2009 did you have four different
8 filter projects that overlapped as far as they were being done
9 at the same time?

11:03:17 10 A Yes.

11 Q And, if you would, the Meridian project, what did the
12 Meridian filter add that had not been in the previous filters?

13 A For the Meridian project, what we set out to do was to
14 add features that would improve caudal migration resistance.

11:03:34 15 So there was some new types of anchors that we were exploring
16 adding onto the filter at that time.

17 Q And how about the Denali project, how is it different?

18 A The Denali project was completely, completely different
19 platform. It's like the next generation platform.

11:03:55 20 That filter is constructed out of a single piece of
21 Nitinol tubing, as opposed to the 12 wires that are welded.
22 So you would take Nitinol tubing, laser weld the pattern into
23 it. Had penetration limiters on it, caudal anchors, cranial
24 anchors, snarable tip, terminally electropolished. So there
11:04:19 25 were a lot of manufacturing improvements that were implemented

DIRECT EXAMINATION - MICHAEL RANDALL

11:04:22 1 on this. There was an advancement in technology.

2 Q And did you plan to do a clinical trial involving the
3 Denali filter?

4 A Yes.

11:04:35 5 Q Did that ultimately come to pass?

6 A Yes.

7 Q Mr. Randall, let me ask you this: The case that we're
8 here for today involves an Eclipse filter that was implanted
9 in August of 2010. Did Bard have the technology and ability
11:04:54 10 to add caudal anchors onto Bard's filters that was ultimately
11 done with the Meridian project at that time?

12 A No, we did not.

13 Q And did Bard have the technology and ability to create a
14 filter completely out of Nitinol tubing like it did with the
11:05:14 15 Denali filter in 2010?

16 A No, we did not.

17 Q Mr. Randall, the jury has heard at various points in the
18 trial about a cascade of events. And is that something that
19 you have heard of in the engineering world?

11:05:34 20 A No, I have not. The only time I've ever heard it is
21 preparing for this case.

22 Q And when -- at certain points in time did Bard look to see
23 whether there was potentially some interrelatedness between
24 various failure modes like tilt, perforation, and fracture?

11:05:53 25 A Yes, we did.

DIRECT EXAMINATION - MICHAEL RANDALL

11:05:54 1 Q And what did Bard conclude about that?

2 A The conclusion is that there is no cascade effect. In
3 fact, when you look at Meridian, you know, initially there
4 was a hypothesis if you stop caudal migration that then leads
11:06:16 5 to stopping tilt, that leads to then potentially, you know,
6 reducing fracture. That did not happen.

7 What happened with Meridian is we stopped caudal
8 migration. But there was still fracture that happened. Very
9 small amount. Still some tilt. Very small amount.

11:06:36 10 So the whole cascade effect, that did not exist.

11 Q And in the current version of the Bard filter, the Denali,
12 the latest technology, do those same failure modalities happen
13 in the Denali filter?

14 A Yes, they do.

11:06:52 15 Q Are you aware of any filter on the market that does not
16 have reports of fracture, migration, or perforation?

17 A I'm not aware of any filter on the market.

18 Q Mr. Randall, is it the goal at C.R. Bard to reduce
19 complications as much as possible?

11:07:08 20 A Absolutely. You're always going to have complications,
21 and what we see is well below 1 percent and we're trying to
22 get it even lower. Anything we can do -- introducing new
23 technologies, modifying processes to make improvements, we'll
24 do.

11:07:25 25 Q And is it possible to completely eliminate things like

CROSS-EXAMINATION - MICHAEL RANDALL

11:07:28 1 fracture, tilt, perforation, migration?

2 A No.

3 Q And even though those things happen with an Eclipse
4 filter, did you believe the risks of the filter outweighed the
11:07:42 5 benefits of the Eclipse filter?

6 A No.

7 MR. ROGERS: Thank you, Mr. Randall. I have no
8 further questions.

9 THE COURT: Cross-examination?

11:08:09 10 MR. STOLLER: Thank you, Your Honor.

11 I'll move the microphones a bit.

C R O S S - E X A M I N A T I O N

12
13 BY MR. STOLLER:

14 Q Good morning, Mr. Randall.

11:08:16 15 A Good morning.

16 Q We've met before. My name is Paul Stoller, I hope you
17 remember.

18 MR. STOLLER: I would like to start, if we can,
19 exhibit with -- Gay, with the last exhibit we saw, which I
11:08:28 20 think is the demonstrative 8482. If you would put that up,
21 please.

22 Could we display to the jury, Your Honor?

23 THE COURT: Yes.

24 BY MR. STOLLER:

11:08:37 25 Q Mr. Randall, I believe you just testified that this is

CROSS-EXAMINATION - MICHAEL RANDALL

11:08:41 1 something that accurately depicts the timeline of various
2 developments of the IVC filters at Bard; correct?

3 A Yeah. To the best of my knowledge, going back and
4 looking at documentation.

11:08:52 5 Q And did you put this together?

6 A I worked with the lawyers to put this together.

7 Q So to the best of your knowledge this is accurate. True?

8 A True.

9 Q You started at Bard in 2006. True?

11:09:04 10 A Correct.

11 Q And you started working heavily in filters in about 2008.
12 True?

13 A 2007.

14 Q Okay. Fair enough.

11:09:11 15 So in 2006, the G2 was on the market when you came to
16 Bard; correct?

17 A Correct.

18 Q And you understood shortly after you became involved with
19 IVC filters that Bard had some problems with caudal migration.
20 True?

11:09:29 21 A Shortly -- I didn't understand that we had problems. I
22 knew we wanted to make enhancements to reduce any
23 complications that we're seeing. So it was caudal migration
24 we were looking at, improve fatigue resistance, improving
11:09:47 25 tilt. So it wasn't that I came in and felt there was issues,

CROSS-EXAMINATION - MICHAEL RANDALL

11:09:49 1 it's what's the next project, how do we make the project
2 better.

3 Q Sir, I'm going to ask you yes or no questions. If you can
4 answer yes or no, please answer yes or no. If you can't
11:09:59 5 answer my question yes or no, just tell me I can't answer your
6 question yes or no, and I'll do my best, if I can, to rephrase
7 the question. Is that fair?

8 A Yes.

9 Q So were you aware in 2006 that Bard had determined that
11:10:13 10 the G2 filter was suffering caudal migration at a rate that it
11 deemed unacceptable?

12 A No, I was not aware.

13 Q Okay. Were you aware in 2008, when you began to work on
14 the G2 Platinum project, that Bard had, with the G2, suffered
11:10:31 15 caudal migrations at a rate that it deemed unacceptable? Yes
16 or no?

17 A I can't answer that yes or no.

18 Q You can't answer whether you were aware in 2008 that that
19 determination had been made?

11:10:46 20 A Yeah, because I don't know if that that determination was
21 made.

22 Q Okay. Fair enough.

23 Let's talk about 2008. And I'm not going to put up
24 the exhibit, but you testified earlier in this trial about the
11:10:59 25 PowerPoint presentation about the effects -- I'm sorry, the

CROSS-EXAMINATION - MICHAEL RANDALL

11:11:04 1 results of the EVEREST trial. Do you recall that?

2 A Yes.

3 Q And in the EVEREST trial, that was a closed study;
4 correct?

11:11:12 5 A What do you mean by closed study?

6 Q It had a defined patient population that was observed from
7 the time of implant until the time the study was concluded.
8 True?

9 A I don't know if it had a defined patient population.

11:11:26 10 There was -- I believe cancer patients were allowed, patients
11 that had pelvic trauma. So I'm not sure I understand what
12 you mean by closed. It was a prospective study.

13 Q Sir, I'm going to -- again, if you can't answer my
14 question yes or no, just tell me, say I can't answer that
11:11:44 15 question yes or no, and I'll do my best to rephrase.

16 A Okay.

17 Q All right?

18 The study you had with the EVEREST trial was 100
19 patients; correct?

11:11:55 20 A I believe EVEREST was -- yes.

21 Q And you knew who those patients were from the time they
22 had their filters implanted until the end of the study. True?

23 A I'm sorry, can you repeat that?

24 Q You knew and identified the patients who had those filters
11:12:10 25 implanted and they were part of the study from the beginning

CROSS-EXAMINATION - MICHAEL RANDALL

11:12:13 1 until the end. True?

2 A Yes.

3 Q So it wasn't a transient population of people in and out
4 and not knowing who was getting filters and who was not;
11:12:22 5 correct?

6 A I cannot answer that question.

7 Q It was a set group of people; you knew who they were.
8 True?

9 A Yes.

11:12:29 10 Q And of those, you followed -- were able to follow through
11 on 83. You lost 17 somewhere along the way for various
12 reasons. True?

13 A I cannot answer that question. I'd like to elaborate if
14 you'd let me.

11:12:48 15 Q The final results you looked at in the PowerPoint
16 presentation that this jury saw earlier in this trial you
17 testified was about 83 patients. True?

18 A Okay, if you say so. True.

19 Q And of those 83 patients, you had 12 percent who had
11:13:01 20 caudal migration. True?

21 A I cannot answer that question because I don't remember
22 all those numbers off the top of my head.

23 MR. STOLLER: Gay, could we pull up Exhibit 1222, I
24 believe.

11:13:20 25 And could you go to the page with the Venn diagram.

CROSS-EXAMINATION - MICHAEL RANDALL

11:13:27 1 There we go.

2 BY MR. STOLLER:

3 Q We see under caudal migration, sir, there are four plus
4 three plus one plus two, so ten patients out of 83 who had
11:13:40 5 caudal migration in that observed study. True?

6 A True.

7 MR. STOLLER: Can I publish this to the jury,
8 Your Honor?

9 THE COURT: Yes.

11:13:49 10 MR. STOLLER: Thank you.

11 BY MR. STOLLER:

12 Q I'm not going to make you do math on the stand, but about
13 12 percent.

14 A Appreciate that. True.

11:13:56 15 Q Would you agree?

16 And you saw in that same study that tilt was in 15 of
17 the 83; correct?

18 A Correct.

19 Q Again, not exact math but about 18 percent. True?

11:14:04 20 A Yes. True.

21 Q And you saw perforation existed in, looks like 12 plus two
22 plus three plus one. So if my math is correct, that is 18 out
23 of the 83; correct?

24 A Correct.

11:14:19 25 Q Twenty-something percent. 23 percent. Is that about

CROSS-EXAMINATION - MICHAEL RANDALL

11:14:22 1 right?

2 A Sure.

3 Q What we see in the middle of the chart is some numbers
4 where they overlap; right?

11:14:30 5 A Correct.

6 Q And you were -- you knew, at least no later than 2008 when
7 you had this PowerPoint presentation put together, those were
8 complications you saw in a closed group of identified patients
9 with this filter. True?

11:14:46 10 A True.

11 MR. STOLLER: Gay, can we go back to the last
12 exhibit, please.

13 Your Honor, may we display again?

14 THE COURT: Yes.

11:14:58 15 BY MR. STOLLER:

16 Q This your timeline. So at least by mid 2008 you knew
17 those things. True?

18 A Yes.

19 Q Okay. And at that time in mid 2008, you are the team
11:15:10 20 leader for the new project, the G2 Platinum; correct?

21 A Correct.

22 Q And your boss at the time, the head of research and
23 development, is Ms. Raji-Kubba. True?

24 A 2008. I believe so.

11:15:28 25 Q In fact, she was your boss all the way through the

CROSS-EXAMINATION - MICHAEL RANDALL

11:15:30 1 development of the Eclipse. True?

2 A Actually, I never reported to her.

3 Q She was the head of R&D, the head of your department.

4 A True.

11:15:37 5 Q If she wasn't your boss, she was your boss' boss; correct?

6 A True.

7 Q So when we look at this chart and we talk about when did

8 you -- you knew back at least as early as 2008 that caudal

9 migration was happening at 12 percent in an identified patient

11:15:53 10 population study by Bard; right?

11 A Yes, I knew that data.

12 Q And but you didn't start anything, at least here according

13 to this, to looking at changing the design or development of

14 that feature until February of 2009; right?

11:16:07 15 A You're talking about for caudal?

16 Q Yes, sir.

17 A The G3 actually had elements for that.

18 Q Okay. Apparently you stopped that, didn't you?

19 A Yeah. That project. It was not successful.

11:16:23 20 Q And then there's a large gap there before we get to

21 February of 2009 when, in the Meridian, we start looking at

22 solving caudal migration. True?

23 A Yeah. There was another idea of how to go about the

24 solution.

11:16:37 25 Q Can you answer my question yes or no, sir. It wasn't

CROSS-EXAMINATION - MICHAEL RANDALL

1 until February of 2009 before you started the work again on
2 trying to solve caudal migration?

3 A Yes.

4 Q And you knew, at least in mid 2008, that we had a
5 significant incidence of caudal migration in the EVEREST
6 study. True?

7 A Can you repeat that?

8 Q You knew in mid 2008 that you had a significant incidence
9 of caudal migration in the EVEREST study. True?

10 A I cannot answer that yes or no.

11 Q You can't say whether 12 percent is a significant
12 incidence?

13 A Significant clinically?

14 Q I'm asking you, sir, do you think 12 percent caudal
15 migration is significant incidence of caudal migration with
16 these filters?

17 A Statistically? Yes.

18 Q Okay. So you knew in July of 2008 you had a significant
19 incidence of caudal migration with the existing filter on the
20 market. True?

21 A Yeah, I would think so. Yes.

22 Q And the next project didn't start for at least a year.
23 True?

24 A No, not true.

25 Q Okay. Fair enough.

CROSS-EXAMINATION - MICHAEL RANDALL

1 But if Bard knew in February of 2006 that it had an
2 unacceptable rate of caudal migration, you didn't actually
3 start the Meridian project until February 2009. True?

4 THE COURT: You said February 2006.

11:18:07 5 MR. STOLLER: I said if they knew in February 2006,
6 which is, Your Honor, the date of the February HHE.

7 BY MR. STOLLER:

8 Q They didn't start the Meridian project until February
9 2009; correct?

11:18:19 10 A I'm sorry, can you repeat that question?

11 Q You know what, I'll move on. I think the jury's seen that
12 evidence.

13 You testified in response to some questions by
14 Mr. Rogers about developing some -- a bench test, I think you
11:18:34 15 said, that twists and compresses and moves the IVC filter in a
16 simulated fashion. Is that true? Did I understand that
17 testimony correctly?

18 A Stretch and compress.

19 Q Stretch and compress. That is something more recent.
11:18:49 20 True?

21 A Define more recent.

22 Q More recent than the Eclipse filter we're talking about in
23 this case.

24 A Correct.

11:18:58 25 Q That test was never run on this filter.

CROSS-EXAMINATION - MICHAEL RANDALL

11:19:04 1 A Not during --

2 Q Let me ask --

3 A Not during the development.

4 Q Not during the development of this filter.

11:19:10 5 A Right.

6 Q Okay. Let me talk to you real quickly about some of the
7 tests you actually testified to about that happened in this
8 case.

9 One of the things you said you went back after you
11:19:18 10 got started, you looked at the design history file for the G2;
11 correct?

12 A Um-hmm. Correct.

13 Q And when you looked at that, did you look at the testing
14 that was done on that filter prior to it being released to the
11:19:30 15 market?

16 A Correct. Yes.

17 Q And one of the things the jury saw earlier today was
18 Exhibit 5037.

19 MR. STOLLER: Gay, could you bring this up.

11:19:40 20 And Mr. Carr testified about this test a bit.

21 Your Honor, this is in evidence. May we display?

22 THE COURT: Yes.

23 MR. STOLLER: Thank you.

24 BY MR. STOLLER:

11:19:56 25 Q Sir, this is the FEA for the G2 filter. Do you recognize

CROSS-EXAMINATION - MICHAEL RANDALL

11:20:01 1 that?

2 A No.

3 Q You don't recognize this document?

4 A No.

11:20:07 5 Q Let's take a look at the second page and see if you
6 recognize it there.

7 Engineering test report ETR-05-02-02. Effect of
8 changes to the Recovery filter and the femoral delivery system
9 on filter stresses based on FEA analysis.

11:20:28 10 Are you familiar with this document?

11 A No, I'm not.

12 Q Would you have reviewed it in 2006 or 2008 when you went
13 back through the DHF, the design history file, for the G2?

14 A No, not to the changes I was making to the Eclipse
11:20:44 15 filter. I would never look at this part.

16 Q Why not?

17 A The changes that I was implementing for Eclipse revolved
18 around the cyclic arm fatigue test that would be conducted,
19 the corrosion analysis that was done on it. So I'm looking
11:21:04 20 at tests, like how it performed previously, and then the
21 change or improvement we're implementing to see then how it
22 stacks up. So I'm not going through the entire review of the
23 design history file. I'm only looking at relevant tests per
24 the change I'm going to be making.

11:21:21 25 Q So it was not relevant to your study for the Eclipse

CROSS-EXAMINATION - MICHAEL RANDALL

11:21:23 1 filter, the FEA that assessed the filter stresses for the G2?

2 A No. Empirical data was more important to me.

3 Q Fair enough. We'll set that aside and talk about that
4 with the jury later.

11:21:38 5 Let's talk about the first test you discussed today,
6 which is Exhibit 8574.

7 MR. STOLLER: Gay, would you put that up, please.

8 Your Honor, I believe this is in evidence. May we
9 publish?

11:21:54 10 THE COURT: Yes, you may.

11 MR. STOLLER: Thank you.

12 BY MR. STOLLER:

13 Q Sir, you described this earlier as the cyclic fatigue
14 testing of the wire; correct?

11:22:02 15 A Correct.

16 Q And the wire here, I believe you testified that this
17 was -- this was the -- you bent the wire; is that correct?

18 A Yeah. This was a bending test of the wire.

19 Q Now, the jury's seen this before so I don't want to go in
11:22:24 20 too much detail into this test, but would you agree with me,
21 sir, this is not a test of the whole wire, it was only a test
22 of the foot. True?

23 A No, this was a test of the wire.

24 Q Let's take a look.

11:22:36 25 MR. STOLLER: Gay, would you turn -- take us to

CROSS-EXAMINATION - MICHAEL RANDALL

11:22:38 1 page 3, please.

2 Let's look at the very top: Purpose.

3 BY MR. STOLLER:

4 Q It says: "The purpose of this study was to compare the

11:22:48 5 fatigue life of the electropolished Vail filter wire to the

6 mechanically ground G2X wire by cyclically bending the ground

7 portion of the wire."

8 Do you see that?

9 Mr. Randall?

11:23:05 10 A Yes, I do.

11 Q I read that correctly. True?

12 A Yes, you did.

13 Q Let's go look under Background. Second paragraph.

14 It says: "the Vail wire" -- excuse me. "The Vail

11:23:15 15 filter wire is individually electropolished by an external

16 supplier and will exhibit a smoother surface along its entire

17 length." This is the part I'd like to focus on, sir.

18 "However, the most evident improvement to the surface finish

19 will be along the tapered and smaller diameter sections of the

11:23:32 20 wire that are formed by the grinding operation."

21 Did I read that correctly?

22 A You have.

23 Q Then it says: "This is because the marks inherent to the

24 grinding operation wire will be smoothed by the polishing

11:23:44 25 process. The portion of the wire" -- sorry, let me start

CROSS-EXAMINATION - MICHAEL RANDALL

11:23:48 1 over. "This portion of the wire forms the filter hooks in the
2 finished device."

3 Did I read that correctly?

4 A You did.

11:23:56 5 Q Then it says: "And as such, this test evaluated fatigue
6 life of the Vail wire in this area in comparison to the G2X
7 filter wire."

8 Did I read that correctly?

9 A You did.

11:24:10 10 Q Okay. Let me ask you --

11 MR. STOLLER: Gay, would you turn to page 6, please.

12 BY MR. STOLLER:

13 Q These are the results. True?

14 A True.

11:24:19 15 Q And if we look at the top table, it tells us G2X filter
16 wire measurements. True?

17 A True.

18 Q The average overall measurement in the wire diameter for
19 the G2X says it's .01042; correct?

11:24:40 20 Do you see overall average?

21 A Yes, I do.

22 Q Let's look at the same table, table 5, for the Vail wire.

23 Do you see that?

24 A Yes, I do.

11:24:53 25 Q Table 5. Vail wire diameter measurements.

CROSS-EXAMINATION - MICHAEL RANDALL

11:24:56 1 Are you with me, sir?

2 A Yes.

3 Q Overall average .01076; correct?

4 A Yes.

11:25:04 5 Q If my math is correct, it's -- whatever the last two
6 digits, it's 32 higher for the Vail wire than for the G2X
7 wire. True?

8 A I'm sorry, could you repeat that question?

9 Q Sure. The last two digits of the Vail wire number are
11:25:21 10 32 -- I've lost -- I won't do my full math, but hundred
11 thousandths of whatever the measurement greater than the G2X
12 filter wire. True?

13 A You're asking how thick the Vail wire is?

14 Q The overall average for the Vail wire was bigger than the
11:25:43 15 overall average for the G2X wire in this comparative study.
16 True?

17 A By .0003.

18 Q Sir, my question is, is it true the wires were not the
19 same size?

11:26:09 20 A I don't agree with that.

21 Q Okay. Let's move on to the next test that you testified
22 about. Exhibit 8546.

23 MR. STOLLER: Your Honor, this is in evidence. May
24 we display?

11:26:27 25 THE COURT: Yes.

CROSS-EXAMINATION - MICHAEL RANDALL

11:26:29 1 BY MR. STOLLER:

2 Q Sir, this was the test you referred to as the beam --
3 rotary beam fatigue test. True?

4 A True.

11:26:37 5 Q And this test is not for the Eclipse, is it?

6 Let me ask you this: Take a look at the "To" line in
7 there. It says To: Design history file, project number 8088.

8 Do you see that?

9 A Yes, I do.

11:26:59 10 Q You know that project number 8088 was not the project
11 number for the Eclipse, don't you?

12 A I forget what the project number for Eclipse is.

13 Q Would 81 -- I've lost my notes. Doesn't matter.

14 You know that that is the project number for the G2
11:27:22 15 Platinum, don't you, sir?

16 A I don't remember the project number. It was years ago.

17 Q Well, the jury will see that later, so let's not spend
18 time on that.

19 We talked a bit about this. At the top there is no
11:27:35 20 TD number; correct?

21 A Correct.

22 Q There is no "From" on this; correct?

23 A Correct.

24 Q There's no signature on this anywhere. True?

11:27:45 25 A True.

CROSS-EXAMINATION - MICHAEL RANDALL

11:27:46 1 Q This is not a final report, it's a draft.

2 A I believe it is a draft.

3 Q And, in fact, we see there's some highlighting even on the

4 first page. It says "ingot Ap." True?

11:27:57 5 A True.

6 Q As an engineer and scientist, you know it's important to

7 go through the full process of a complete formal test before

8 you come to final conclusions. Would you agree with that?

9 A True.

11:28:11 10 Q In fact, at Bard you have policies and procedures that

11 require people to sign off on a test report before it's

12 considered final. True?

13 A If there is a test protocol, you would. But we do a lot

14 of tests where it's not on protocol.

11:28:30 15 Q If you're going to rely on it for something related to the

16 final design validation, verification, or determinations with

17 respect to marketing claims, you're going to have to go

18 through that process. True?

19 A If it's -- yeah, if it's going to be used for that.

11:28:46 20 Q You conduct tests on a regular basis that aren't

21 necessarily used for purposes of substantiating claims about a

22 product. Is that fair?

23 Let me withdraw the question. I'll ask a different

24 question.

11:29:00 25 If you're going to test something in order to verify

CROSS-EXAMINATION - MICHAEL RANDALL

11:29:06 1 or substantiate a claim, it has to go through formal process.
2 True?

3 A Yes. We do have formal process.

4 Q And this document did not. True?

11:29:20 5 A This is just a draft. I don't know where the original's
6 at. But there's also, I believe --

7 Q Sir --

8 A -- a report from Johnson Matthey or the person who
9 conducted the rotary beam test.

11:29:31 10 Q Sir, my question to you is, this is not a final report
11 that's been through that process. True?

12 A This is not a report. Correct.

13 Q Part of the reason you go through that process is to
14 ensure that the tester, whoever conducted the test, followed
11:29:43 15 the protocol. True? One of the reasons.

16 A I cannot answer that question you have --

17 Q Okay. One of the reasons you go through formal process is
18 to ensure the accuracy of the results of the test. True?

19 A True.

11:29:59 20 Q Let's talk about next Exhibit 8359.

21 MR. STOLLER: And, Your Honor, this is in evidence.
22 May we display to the jury?

23 THE COURT: Yes.

24 BY MR. STOLLER:

11:30:21 25 Q You testified, sir, to this. This is the saluting arm

CROSS-EXAMINATION - MICHAEL RANDALL

11:30:23 1 test; correct?

2 A Cyclic arm fatigue test.

3 Q This is what you described to the jury as the saluting arm
4 test. True?

11:30:37 5 A I said this is a test for a cyclic arm and the
6 deflections raise the arm up here, almost like a saluting
7 fashion. But I didn't say this is the saluting arm test.

8 Q Again, sir, if -- you can answer yes or no. If I'm wrong,
9 tell me no. If I'm right, tell me yes. If you can't answer
11:30:54 10 say I don't know or I can't answer that.

11 Let me ask you this question: Did you internally
12 refer to this report as the saluting arm test, or have you
13 heard it referred to as the saluting arm test? This test.

14 A No.

11:31:08 15 Q No. Okay. Well, I'll tell you the jury has heard it
16 referred to as the saluting arm test. Does that make sense to
17 you given that the -- the way the filter arms are moved in
18 this test?

19 A Sure.

11:31:21 20 Q Sure. And you said that this test was one of the things
21 that demonstrated the superior performance of the Eclipse
22 filter as against the G2X. Is that true?

23 A True.

24 Q And if we look at page -- I'm not going to go through
11:31:36 25 this -- well, let's do it. Let's quickly go through it.

CROSS-EXAMINATION - MICHAEL RANDALL

11:31:39 1 MR. STOLLER: Can we go, Gay, quickly to page 6.

2 BY MR. STOLLER:

3 Q And this shows that the overall average before the wires
4 fractured for the G2X were 440 and the overall cycles before
11:31:55 5 the wires fractured for the filter -- I'm sorry, for the Vail,
6 which was the Eclipse, were 719. True?

7 A True.

8 Q And that was the basis of your conclusion that the Eclipse
9 filter performed better than the G2X; right?

11:32:18 10 A True.

11 Q But you knew, sir, you had conducted a similar test on the
12 G2X previously; right?

13 A Yes, there was cyclic arm fatigue done.

14 Q In fact, let's --

11:32:34 15 MR. STOLLER: Gay, could we please look at
16 Exhibit 5385.

17 Your Honor, I believe this is in evidence. May we
18 display to the jury, please?

19 THE COURT: Yes.

11:32:51 20 BY MR. STOLLER:

21 Q Sir, this is Exhibit 5385, which is the G2 Express filter
22 arm fatigue comparison test. True?

23 A True.

24 Q And you are --

11:33:00 25 MR. STOLLER: Gay, if you'll take that down, please.

CROSS-EXAMINATION - MICHAEL RANDALL

11:33:02 1 BY MR. STOLLER:

2 Q You're one of the people on the release panel there
3 underneath it. True?

4 A True.

11:33:07 5 Q And, in fact, if we go to page 2 --

6 MR. STOLLER: Sorry, Gay, I'm moving pretty quickly.

7 BY MR. STOLLER:

8 Q If we go to page 2, you're a signatory on this document:
9 Mike Randall under R&D. True?

11:33:19 10 A True.

11 Q And this test is the same test conducted on the Eclipse
12 for the G2, except this one was conducted in 2007; correct?

13 A I'd have to confirm on the test method if they're exactly
14 the same. It's the same name, though.

11:33:36 15 MR. STOLLER: Well, let's go quickly, Gay, if you
16 would, to page -- I have a different page. 3 of 11. I
17 believe it's page 5. And -- no. Next page. Sorry.

18 BY MR. STOLLER:

19 Q If we go up at the top and References, we'll see the test
11:33:56 20 method; correct? TM1133800; right?

21 A Right. Rev. 0.

22 Q And if that test method is the same test method as used in
23 the Eclipse one, they're the same. True?

24 A They would be the same, yes.

11:34:20 25 MR. STOLLER: Let's look, Gay, if we could, two pages

CROSS-EXAMINATION - MICHAEL RANDALL

11:34:21 1 in. Three pages in, I'm sorry. 6 of 11. So it would be
2 page 9.

3 BY MR. STOLLER:

4 Q The jury's seen this before as well, sir, but if we look
11:34:32 5 at the G2 Express filter results on the saluting arm test --

6 MR. STOLLER: Just the top table, if you would, Gay.

7 Thank you.

8 BY MR. STOLLER:

9 Q -- that in that time the G2 Express averaged 668 cycles
11:34:49 10 before they broke. True?

11 A True.

12 Q And would you agree with me, without doing a lot of math,
13 668 is fairly close to 710, on average. True? Maybe
14 statistically the same.

11:35:05 15 A They're not statistically the same because they're not
16 the same test. You have to do them at the same time.

17 Q Sir, you ran the same test on the same machine, did you
18 not?

19 A I don't know what machine this was ran on.

11:35:22 20 Q Did you have two different machines to run this test?

21 A We have a fixture and then it's whatever Instron can be
22 used. I'm not sure what Instron test this is used on.

23 Q But let me ask this, sir: This test in 2009 -- excuse me,
24 2007, tells you that the G2 Express on that saluting arm test
11:35:45 25 lasted an average of 668 average cycles before the arms

CROSS-EXAMINATION - MICHAEL RANDALL

11:35:50 1 fractured. True?

2 A Yes. True.

3 Q And you knew in 2009 when you conducted the saluting arm
4 test on the Eclipse comparison to the G2X that the result then
11:36:03 5 was 440; correct?

6 A Yes.

7 Q Did you go back and look at, hey, maybe we should rerun
8 those tests given we've only used 15 samples and see why we're
9 getting different results on the G2 Express from one test to
11:36:18 10 the next?

11 A No.

12 Q Let's look, sir, at the last test you testified about,
13 which is 8358.

14 MR. STOLLER: And, Your Honor, I believe this is in
11:36:37 15 evidence. May we display it to the jury?

16 THE COURT: Yes.

17 BY MR. STOLLER:

18 Q Sir, this is what you described as the flat plate fatigue
19 test and corrosion testing. True?

11:36:48 20 A True.

21 Q I'd like to talk about those in two parts. And I'd like
22 to talk about corrosion examination first, if that's okay.

23 A Sure.

24 Q The corrosion examination is you just look to see if the
11:36:58 25 acidic qualities under which you had these testing done chewed

CROSS-EXAMINATION - MICHAEL RANDALL

11:37:01 1 away at the device. True?

2 A Yeah, in layman's terms. True.

3 Q It was not to determine whether there was a fracture as a
4 result of fatigue in that testing; right? The corrosion
11:37:13 5 testing was not aimed at determining whether the device would
6 fatigue by fracture. True?

7 A Hmm.

8 Q Excuse me, I asked that wrong. Fracture by fatigue.

9 A Yeah, it was -- it was a fracture -- yeah. We're looking
11:37:33 10 at if you fatigued it, would you get a fracture in a
11 corrosive environment.

12 Q But the part of examining the corrosive qualities was to
13 see -- not to see whether the fatigue had caused corrosion, it
14 was whether the acidic environment had caused corrosion.

11:37:50 15 True?

16 A Yes.

17 Q Okay. I want to focus on the flat plate part of this.
18 This was not a comparative test. True?

19 A True.

11:37:58 20 Q This was a test where you took the device and you put it
21 in a set of conditions and you squeezed it, effectively, to
22 see over time whether that squeezing and back and forth would
23 cause fatigue and result in fracture. True?

24 A True.

11:38:12 25 Q Okay. And as an engineer, you know, sir, that different

CROSS-EXAMINATION - MICHAEL RANDALL

1 angles and different conditions can affect the amount of
2 stress experienced by a device. True?

3 A True.

4 Q And so the stress experience that you measured by that
5 device was the device sitting equally balanced in the tube.
6 True?

7 A We -- we biased it to put the highest stress point in
8 line with the greatest amount of deflection. So we tried to
9 put it in a position where it saw the most stress.

10 Q Okay. But you know, sir, that if you take something, for
11 example, and you were to -- you were to tilt it significantly,
12 that can change the amount of stress it experiences. True?

13 A It could potentially, yeah.

14 Q It could. And if it endothelializes, it could change the
15 amount of stress experienced at different places. True?

16 A Theoretically, yeah.

17 Q Well, if you take something longer and make it shorter,
18 that increases the stress; right?

19 A It depends on how that geometry's interacting with the
20 stress.

21 Q Okay. But if I have a ruler and I bend it and it's a long
22 ruler, there's less stress on it as a whole than if I have a
23 short ruler and use the same amount of force on it. You would
24 agree with that, wouldn't you?

25 A If you use the same amount of force?

CROSS-EXAMINATION - MICHAEL RANDALL

11:39:42 1 Q Yes, sir.

2 A And apply it at the end of a long ruler versus short
3 ruler what the stress would be?

4 Q Yes, sir.

11:39:48 5 A I think it would be lesser if it's longer.

6 Q If I -- I'm not going to get into this.

7 Let me ask you this question: This testing didn't
8 simulate endothelialization. True?

9 A No.

11:40:07 10 Q And it didn't simulate perforation of the device. True?

11 A No.

12 Q It didn't simulate significant tilt of the device. True?

13 A True.

14 Q And would you agree with me, sir, that the bench testing
11:40:19 15 you performed should predict as closely as possible what
16 happens to the device in the real world?

17 A Sure.

18 Q And the way it's going to perform in people?

19 A Sure.

11:40:38 20 MR. STOLLER: No further questions. Thank you.

21 THE COURT: Redirect?

22 MR. ROGERS: None, Your Honor.

23 THE COURT: Okay. Thank you, sir. You can step
24 down.

11:40:58 25 MS. HELM: Your Honor, before we call our next

11:41:00 1 witness may we approach on just a little administrative issue?

2 THE COURT: Yes.

3 (Bench conference as follows:)

4 MS. HELM: It doesn't take a cast of thousands for
11:41:20 5 this.

6 I just wanted to let you know this video is 22
7 minutes long and maybe we could play the whole thing before
8 lunch.

9 THE COURT: Is there a problem stopping at noon?

11:41:31 10 MS. HELM: No. I just wanted to let you know.

11 THE COURT: Let's just stop at noon and continue
12 after lunch.

13 MS. HELM: Okay.

14 (Bench conference concludes.)

11:41:42 15 THE COURT: Thanks, ladies and gentlemen.

16 MS. HELM: Your Honor, at this time the defendants
17 call William Little by video deposition.

18 There are five exhibits to Mr. Little's deposition,
19 two of which have been previously admitted. They are 1616,
11:42:01 20 which is Deposition Exhibit 2003; and 1621, which is
21 Deposition Exhibit 2009.

22 At this time we move for admission of Exhibit 1618,
23 which is deposition Exhibit Number 2005; Exhibit 2045, which
24 is deposition Exhibit 2002; and Exhibit 1617, which is
11:42:33 25 Deposition Exhibit 2004.

11:42:38 1 THE COURT: Any objection?

2 MR. CLARK: No, Your Honor.

3 Did you say 1618 as well?

4 MS. HELM: Yes.

11:42:44 5 THE COURT: Okay. Those are admitted.

6 (Exhibits 1617, 1618, and 2045 admitted.)

7 MS. HELM: William Little was global vice president

8 of marketing at Bard Peripheral Vascular from 2008 to 2012.

9 Prior to his time at Bard, Mr. Little worked in marketing at

11:43:00 10 medical device manufacturer Boston Scientific.

11 Since leaving Bard in 2012, Mr. Little has held

12 various senior-level positions in marketing at St. Jude

13 Medical, a medical device manufacturer which is a division of

14 Abbott.

11:43:18 15 (Video testimony of William Little played.)

16 THE COURT: Stop the video at this point.

17 We will resume at 1 p.m. and will excuse the jury.

18 (The jury exited the courtroom at 12:00.)

19 THE COURT: Counsel, is there a time allocation on

12:00:03 20 the video?

21 MS. HELM: Yes, Your Honor. Six minutes should be

22 allocated to the plaintiff.

23 MR. CLARK: That's correct, Your Honor.

24 THE COURT: All right. As of now, plaintiff has used

12:00:43 25 27 hours and 15 minutes. And defendants have used 21 hours

12:00:48 1 and 54 minutes.

2 We will see you at 1 o'clock.

3 MR. O'CONNOR: Your Honor, can we talk about the time
4 issue at some point today?

12:00:59 5 THE COURT: Yes.

6 MR. O'CONNOR: Your Honor, respectfully, we think
7 that we should receive some additional time back. There's
8 been some orders and rulings in this case that have
9 understandably resulted in a number of sidebars, and we have
12:01:16 10 done our best on our side to be time efficient. But because
11 of the ruling -- I'm sorry. Because of the way the rulings
12 have gone and the way the evidence has come in and the way
13 we've had to navigate with witnesses, we think that we should
14 receive some of that time back for us.

12:01:38 15 THE COURT: What time back are you talking about?

16 MR. O'CONNOR: Well, I think at least, at least an
17 hour and a half back.

18 THE COURT: Back from where?

19 MR. O'CONNOR: From the sidebars, from the time that
12:01:48 20 we spent with Modra laying the foundation to get this evidence
21 in that we're finally getting in.

22 We don't think it was a waste of time, we just think
23 trials -- things happen that are unpredictable. And with the
24 rulings and the things that have changed the way the evidence
12:02:05 25 came in or the landscape or the evidence that was going to be

12:02:10 1 decided later, it's caused a number of sidebars and it's
2 caused us to have to rethink and redo the way we presented our
3 case.

4 And so we think we've acted in good faith and tried
12:02:22 5 to comply with the clock, but under the circumstances, with
6 our burden of proof, we think that under these circumstances
7 there should be time allotted back to us.

8 THE COURT: Comment from the defendants.

9 MR. O'CONNOR: To both sides.

12:02:35 10 MR. NORTH: I don't think we need additional time,
11 Your Honor. We would object, just as we did in Booker.

12 I would note for the record that this Court issued a
13 warning in a previous order on a motion in limine indicating
14 the Court intended to strictly adhere to the time limitations
15 this time.

16 Without questioning -- I mean it's not my place to
17 question how the plaintiffs try their case, but I would note
18 today, with only two hours left, approximately, they spent
19 over approximately an hour cross-examining two witnesses they
12:03:06 20 had on the stand two weeks ago for a combined three and a half
21 to four hours already, and spent another hour crossing them
22 today.

23 I would also draw the Court's attention to the
24 *General Signal Corporation* case, Ninth Circuit case that we
12:03:21 25 cited in the pretrial order, where the Ninth Circuit ruled in

12:03:25 1 that situation it would be unfair to provide the plaintiff
2 additional time after the defendant had already made strategic
3 decisions based on the Court's original allocation.

4 THE COURT: All right. I will think about this
12:03:36 5 issue. I'll let you know when I come back from lunch.

6 See you at 1 o'clock.

7 MR. O'CONNOR: Thank you.

8 (End of a.m. session transcript.)

9 * * * * *

C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 30th day of May, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter